"DATA PRIVACY AND PATIENT CONFIDENTIALITY IN ELECTRONIC HEALTHCARE SYSTEM: WITH SURVEY AND ANALYSIS ON DATA PRIVACY AND PATIENT CONFIDENTIALITY"

A DISSERTATION TO BE SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF DEGREE OF MASTER OF LAWS

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LIST OF ABBREVIATIONS

DCGI: Drug Controller General of India

DPA: Data Protection Act

ECHR: European Court of Human Rights

EHR: Electronic Health Record

EMR: Electronic Medical Record

GMC: General Medical Council

HIPPA: Health Insurance Portability and Accountability Act

HITECH: Health Information Technology for Economic and Clinical Health

HPV: Human Papilloma Virus

ICMR: Indian Council of Medical Research

IEC: Institutional Ethics Committee

IPC: Indian Penal Code

IPCC: International Pharmaceutical Privacy Consortium

IRB: Institutional Review Board

IRDA: Insurance Regulatory and Development Authority

MARPs: Most at Risk Populations

MCI: Medical Council of India

MTP: Medical Termination of Pregnancy

NACO: National AIDS Control Organization

NIST: National Institute of Standards and Technology

PATH: Program for Appropriate Technology in Health

PCPNDT: Pre-Conception and Pre-Natal Diagnostic Techniques

RTI: Right to Information

SHA-1: Secure Hash Algorithm 1

CASE LAWS

- AG v. Guardian Newspapers (No.2) [1990] 1 A.C. 109.
- Ashworth Hospital Authority v. MGN [2002] UKHL 29.
- B.K. Parthasarthi v. Government of Andhra Pradesh, AIR 2000 A.P 156.
- Black v. The Information Commissioner (2007) 98 B.M.L.R. 1.
- Bolam v Friern Hospital Management Committee (1957) 2 All ER 118.
- C v. C [1946] 1 All E.R. 562.
- Campbell v. MGN, [2004] UKHL 22.
- Canterbury v. Spence 464 F.2d 772 (D.C. Cir. 1972).
- Cf. O'Brien v. Cunard (1891) 28 N.E. 266.
- Common Services Agency v. Scottish Information Commissioner, (2008) UKHL 47.
- Coco v. Clark [1968] F.S.R. 415 at 419.
- Cornelius v. De Taranto [2001] E.M.L.R. 12.
- Durant v. Financial Services Authority, 2003 EWCA Civ 1746.
- Gaskin v. United Kingdom (1990) 12 E.H.R.R. 36.
- Gillick v. West Norfolk and Wisbech Area Health Authority, (1986) AC 112, HL.
- Glass v. UK [2004] 1 ELK 1019.
- Govind vs. State of M.P., 1975 SCR (3) 946.
- Kapadia v. London Borough of Lambeth, [2000] 57 BMLR 170.
- Kharak Singh vs. State of U.P, 1964 SCR (1) 332.
- Lewis v. Secretary of State for Health, [2008] EWHC 2196.

- Mr. Surupsingh Hrya Naik v.State of Maharashtra, AIR 2007 Bom 121.
- Mr. X v. Hospital Z, 1988 8 SCC 296.
- Ms. X vs. Mr. Z &Anr., 96 (2002) DLT 354.
- M. Vijaya v. Chairman and Managing Director, Singareni Collieries Co. Ltd., AIR 2001 AP 502.
- Neera Mathur v. Life Insurance Corporation (LIC), AIR 1992 SC 392.
- Pfizer Corporation v. Ministry of Health [1965] A.C. 512.
- Pratt v. Davis, 118 Ill. App. 161 (1905). aff'd. 224 Ill 300, 79 N.E. 562 (1906).
- Radiological & Imaging Association v. Union of India, AIR 2011 Bom 171.
- R. (Axon) v. Secretary of State for Health, [2006] EWHC 372.
- R. v. Department of Health Ex p. Source Informatics [1999] 4 All ER. 185.
- Re C, [1990] Pam.
- Re Z [1997] Farm.
- R. (S) v. Plymouth City Council, [2002] EWCA Civ 388 esp.
- R (on the application of B) v. Stafford Combined Court, [2006] EWHC 1645 (Admin).
- Reynolds v. Health First Medical Group [2000].
- S and Marper v. UK, (2009) 48 EHRR 50, ¶ 66-67.
- Saltman Engineering v. Campbell Engineering [1963] 3 All ER. 413.
- Samira Kohli v. Dr Prabha Manchanda, (2008) 2SCC 1.
- Schoendorff v. New York Hospital, 211 N.Y. 125, 105 N.E. 92 (1914).
- Sharda v. Dharmpal, AIR 2003 SC 3450.
- Shri G.R. Rawal v. Director General of Income Tax (Investigation), No. CIC/AT/A/2007/00490.

- Sidaway v Bethlem Royal Hospital Governors & Ors. (1985) 1 All ER 643.
- Smt. Selvi and Ors. v. State of Karnataka, (2010) 7 SCC 263.
- Sorrel v. IMS Health Inc., 131 S. Ct. 2653 (2011).
- Stephens v. Avery [1988] Ch. 449.
- Stone v. South East Coast SHA, [2006] EWHC 1608.
- Szuluk v. United Kingdom, (2009) 108 BMLR 190.
- Venables v. NGN [2001] Pam.
- X Health Authority v. Y [1988] 2 All ER. 648.
- Yepthomi v. Apollo Hospital Enterprises Ltd., AIR 1999 SC 495.
- Z v. Finland, (1997) 25 EHRR 371.

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INTRODUCTION

“Once you’ve lost your privacy, you realize you’ve lost an extremely valuable thing.”- Billy Graham

CHAPTER- I

INTRODUCTION

Trust is tough to achieve and straightforward to lose. Medical remedy depends on trust. Patients and potential sufferers ought to take into account that those to whom they're going to for scientific recommendation, prognosis, and treatment ar equipped and discreet. even as few may visit those they settle for as true with to be incompetent, few would visit people who had been unable or unwilling to carry a patient's intimate info to themselves. promptly liberating patient details to the relief of the planet while not the patient's consent may be probably to embarrass, offend, stigmatise, and, in the end, deter citizenry from trying to find scientific recommendation and remedy. It need to threaten the additional true, people' rights and hobbies, and variety of virtues. As a result, as regards to all moral theories can realise the lifestyles of associate obligation of confidentiality. Such associate obligation can now not be absolute. The failure to launch facts roughly a patient's physical or mental state will itself threaten the additional high, people's rights and interests, and lots of virtues. A blanket and absolute responsibility of confidence would forestall a health professional from revealing information this can be very important for different health specialists to treat the affected person effectively. Exceptions to the overall responsibility of confidentiality need to move past patient consent if speech act is to be approved to defend others from associate affected one who, say, intends to putting to death or contains a rather infectious illness.

1.1 Statement of Problem-

Technology makes sensitive info additional accessible to additional individuals, with ensuing edges and dangers. Automating tending info and also the emergence of the computer-based patient record-keeping have brought the problems of privacy and confidentiality to the fore-front.
In India, the confidentiality clauses in patient-doctor relationship are presently regulated through the "Code of Ethics Regulation of the drugs or Dental Councils". These rules have provisions for penalty by the various statutory bodies however the sanctions are weak and ineffective.

Ordinarily professionals mustn't produce, update or store records on their personal electronic devices (e.g. Computers, cell phones and flash drives) or on personal on-line accounts. within the absence of a correct framework, there are nearly no principles governing however this info ought to be hold on or used, resulting in the chance that medical information are going to be commercial and abused.

Wherever attainable, these health records are to be joined to the Aadhaar range and as recent reports reveal, the legal framework governing the utilization of aadhaar is murky yet, adding another layer of unsure privacy implications. there's no clear framework governing electronic medical records and also the manner during which they're collected and used, and nor are there remedies for information breaches because of negligence of public hospitals.

1.2 Objective of Study-

The purpose of this analysis study is to formulate a whole guide that maps the synthesis, form and implementation of privacy rules inside the tending quarter in Asian nation. It lines the house regulation relating various aspects of the tending region and also the distinctive provisions of the regulation that facilitate the security of the privacy of parents that grant their non-public records yet as genetic material to institutions of tending, either for the explanation of trying to find remedy or to form contributions to analysis. the design at consequently targets to collate the prevailing structures of privacy safety within the shape of laws, pointers and hints with special reference to the present electronic scientific records gathering and storing techniques and whether or not those laws are actually effective in assembly the required necessities of privacy protection inside the last time. Further, a survey has been taken to induce a more robust understanding regarding the overall knowledge/awareness amongst individuals regarding their right to privacy and confidentiality and information protection within the tending system and to lift awareness regarding a similar through this survey.

1.3 Research Question-

Medical confidentiality promotes the character's medical autonomy, via sheltering those in search of virtuously debatable medical aid from outside grievance and interference with selections. With the emergence of recent technological advances inside the storing of patients personal clinical records the electronic storage of medical statistics has uncovered individuals to the threat of identification at various ranges of facts assortment and records process. Keeping this in mind this paper assesses-

- Whether the innovative statistics safety rules create a distinction to patient privacy in Asian nation. The policies limit the unauthorized transfer of medical info and medical records as misuse of sensitive facts.

- It goals to look at the prevailing mechanisms of privacy protection and also their pragmatic application in standard practices and the approach will the definitive coverage gaps inside the present framework is also crammed by suggests that of developing a contrivance that's economical in its success of the larger goal of the realization of the proper to Privacy at a private, kingdom and institutional stage.

- It examines the models of privacy safety evolved within the international organisation, uk and u. s. and therefore the extent to that these contribute toward protecting affected person records and what provisions will Asian country soak up to create their Electronic Health Record system safer.

- This paper conjointly presents a prime level read of numerous data protection regimes, determined with the help of associate degree analysis of the Indian role on facts privacy.

- Towards the top of this paper a survey report has been hooked up that aims at explaining the viewer concerning the amount of awareness amongst the final public concerning their rights as a patient and a neighborhood with general data has been shaped within the survey concerning

identical to assist unfold awareness

Hypothesis-

The research lays down the subsequent hypothesis:

1.The many sides with reference to patient privacy have return to the fore in massive half via precise case legal tips that area unit reflective of a dynamic social organisation, one that seeks to reconcile the socio economic rights that when dominated society with person interests that it's slowly return to appreciate

2.the correct of a personal to disclose the character of his illness, the freedom of a lady not to be forced to travel through a blood take a glance at, the physical autonomy to work out to endure youngsters or now not, the decisional privacy on the topic of the termination of a being pregnant and therefore the tutelary rights of individuals to their youngster area unit positive contentious components of care that have made the porous interface among the correct to privacy and therefore the need for clinical treatment.

3.it's on this context that this study pursuits to dig into the current easy form of home law, case laws and rules and their next package to be ready to decide vital gaps at intervals the formulation of Law and Policy.

4.The survey conducted aims at assessing the amount of awareness amongst individuals with regards to their medical information privacy and confidentiality and therefore the rights as a patient that area unit out there within the care system.

5.Further, it conjointly provides a thought on what quantity the health professionals follow the essential rules of ethics in reality with their patient's i.e. explaining and inquiring for their consent, respecting their privacy and not pampering in any unethical sharing.

1.4 Research Methodology-

The analysis style that I even have adopted is each descriptive study and empirical study, wherever i'll describe concerning the conception of consent specific to medical analysis and treatment that continues to be alien to several medical researchers and practitioners and to a lot of Indians. The doctor– patient relationship in Asian country is ruled a lot of by trust wherever the doctor is that the authoritative person. Therefore, the good thing about consent doesn't reach all patients in day-after-day practice. conjointly with the fast conversion of the medical records and body informationbases I reviewed privacy problems close the employment of electronic data collected in routine medical aid, and regarded advanced approaches to minimizing potential privacy violations once information is employed for medical analysis.

The method of my study is belief. The study is only supported Secondary information. the info needed for the study are going to be collected from Books, Journals and reports, websites, articles and analysis papers.
As for the survey I've used quantitative analysis through the cross-sectional survey technique by a form that was shared through e-mail and different social-media sharing platforms. The survey report i.e. the analysis and therefore the interpretation of the collected information has been added towards the top of this report.

CHAPTER-II CONCEPTUAL FRAMEWORK

“Privacy is not something that I’m merely entitled to, it’s an absolute prerequisite.” - Marlon Brando

CHAPTER-II

CONCEPTUAL FRAMEWORK

2.1 HISTORY-

The foundation of the normal theory of consent to treatment lies within the law of battery, and is found in choices people courts as early as 1905.1 Justice Cardozo offered what has become maybe the known statement of the principle of consent within the one914 ny

> case of Schoendorff v. ny Hospital:2 'Every soul of adult years associate degreed sound mind contains a right to work out what shall be through with his own body: associate degreed a medico WHO performs an operation while not his patient's consent commits an assault. Consent could also be specific or tacit. specific consent is associate degree oral or written authority by the patient to render the planned treatment. Consent could also be tacit from the conduct of the patient in an exceedingly explicit case, or from the appliance of law, to sure factual things. A patient WHO voluntarily submits to treatment underneath circumstances which might indicate awareness of the planned treatment impliedly authorizes the treatment, even while not specific consent. A patient WHO presents himself or herself at the doctor's workplace for a routine procedure implies his or her consent to treatment

The Pledge of Florence Nightingale:

"I solemnly pledge myself before God and within the presence of this assembly to pass my life in purity and to apply my profession reliably.

I will abstain from no matter is harmful or mischievous, and can not take or wittingly administer any harmful drug.

I will do bushed my power to elevate the quality of my profession, and can hold in confidence all affairs committed to my keeping, and every one family affairs coming back to my information within the apply of my occupation

With loyalty can I endeavour to assist the medical man in his work and devote myself to the welfare of these committed to my care."3

1 Pratt v. Davis, 118 Ill. App. 161 (1905). aff'd. 224 Ill 300, 79 N.E. 562 (1906).

2 211 N.Y. 125, 105 N.E. 92 (1914)

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The origin of the confidential relationship between doctor and patient and therefore the doctor's duty to respect this relationship is found within the oath. Matters that pertain to a patient's health area unit personal to it individual. From a duty-based perspective, confidentiality serves to emphasize the patient's right to privacy. From a consequentialist purpose of read, effective care will solely be provided if a patient are often honest with the doctor and therefore the foundation of this honesty is based upon the implicit understanding that the doctor won't disclose personal data. this could be significantly vital and relevant once ascertaining sexual history, psychological and familial factors that pertain to health. Some medical enquiries are often intrusive on a personality's non-public life however however necessary at intervals that exact context, and patients would be unlikely to disclose such data unless they were assured of confidentiality.

From a utilitarian perspective, the confidential doctor-patient relationship serves to encourage people to hunt medical recommendation. The absence of confidentiality would deter some patients from seeking treatment, and therefore the duty of confidentiality may be even on this basis alone. However, this relationship should be thought-about at intervals the context of shut relationships and a few patients might like to not keep data secret from their immediate relatives or shut friends. usually|this can be} often seen in clinical apply wherever a patient arrives for a consultation with a relative or an admirer, ANd this could be significantly relevant in things wherever the doctor has got to break dangerous news or wherever there's an underlying serious medical condition. The duty of confidentiality, however, isn't absolute. to produce adequate medical aid, aspects of the patient's medical condition can have to be compelled to be shared with alternative health-care professionals. moreover, whereas there's a plain advantage in maintaining confidentiality for the patient, there could also be circumstances wherever the duty of

confidentiality are often overridden within the public interest.[4]

2.1.1 International Code of Medical Ethics:

Duties of a Doctor in general-

1. A Doctor should always maintain the very best standards of skilled conduct.

2. A Doctor should not permit himself to be influenced simply by motives of profit.

3. the subsequent practices ar deemed unethical:

* Any self-advertisement, except like is expressly approved by the national code of medical ethics.
* Taking half in any arrange of medical aid during which the doctor doesn't have skilled independence.
* To receive any cash in reference to services rendered to a patient aside from the acceptance of a correct skilled fee, or to pay any cash within the same circumstances while not the information of the patient.

4. beneath no circumstances could be a doctor allowable to try to to something that will weaken the physical or mental resistance of a personality's being except from strictly therapeutic or prophylactic indications obligatory within the interest of the patient.

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3 Lyon's: Medical Jurisprudence and Technology, 101-102 (11th Edition, Revised by Dr. T.D. Dogra, Professor and Head of Dept. of Forensic Medical & Toxicology, AIIMS, New Delhi, Delhi Law House Publication).

4 Jo Samanta, Medical Law, 70-81 [Ash Samanta (Contributor), 2nd ed., Macmillan Law Masters, 2015].

5. A doctor is suggested to use nice caution in commercial enterprise discoveries. a similar applies to strategies of treatment whose worth isn't recognized by the profession.

6. once a doctor is termed upon to present proof or a certificate he ought to solely state that that he will verify.

Duties of doctor to the sick:

1. A doctor should always bear in mind the importance of conserving human life from the time of conception till death.
2. A doctor owes to his patient complete loyalty and every one the resources of his science. Whenever AN examination or treatment is on the far side his capability he ought to summon another doctor UN agency has the required ability.
3. A doctor owes to his patient absolute secrecy concerning, that that has been confided in him or that he is aware of owing to the boldness reposed in him.
4. A doctor should provide necessary treatment in AN emergency, unless he's assured that it will and can be by others.

Duties of doctors to each other

1. A doctor ought to behave towards his colleagues, as he would have them behave towards him.
2. A doctor should not tempt away patients from his colleagues.5

2.2 THE GENERAL DUTY TO PROTECT MEDICAL INFORMATION-

Most, if not all, can have to be compelled to consult a medical man at it slow or another. it's going to preferably be routine, like treatment for 'flu' or it's going to be for a few matter a lot of serious, or a lot of intimate. it's going to be a time once a patient won't wish the knowledge to be illustrious to others and will be a time once the patient is susceptible to suggestion and pressure. The doctor are told one thing secret: the fifteen year-old woman seeking contraceptive recommendation while not her parents' approval, or knowing that the fogeys can ne'er approve of such a thing; the patient UN agency suspects infection with the AIDS virus and needs to be tested for the illness. that a lot of alternative examples may be (and can be) given of AN equally contentious nature shows the elemental sensible nature of the thought of confidentiality. A patient could also be embarrassed by a selected ill health and easily not wish anyone to grasp regarding it. The condition might mean the patient might become the topic of narrow-minded social stigma. it would have a prejudicious result on current or prospective employment or the gaining of insurance cowl. These are simply a couple of the sensible impacts of the doctor not keeping a secret.

There also are potential prejudicious effects within the doctor keeping all data on the patient strictly confidential: the doctor UN agency doesn't inform the police, when asked, that a selected patient, suspected of rape, has recently received treatment for deep facial scratches; the doctor UN agency tells nobody that AN AIDS-infected patient has simply left the surgery vowing to 'infect the world' by injecting strangers with contaminated blood; the doctor UN agency refuses to unharness data on a patient to a physician referred to as in to diagnose that patient's mysterious however dangerous ill health. These ar the sensible dilemmas which will be faced. however what of the moral justification for the existence of confidentiality?6

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5 Supra Note 3.

6 Michael Davies, Textbook on Medical Law, 29-55 (2nd Ed. Paperback 1998).

Moreover, in a very attention context, patient confidentiality and therefore the protection of privacy is that the foundation of the doctor-patient relationship. Patients should feel snug sharing non-public data regarding their bodily functions, physical and sexual activities, and medical history.7 attention personnel should acquire, process, store, retrieve and transfer clinical, body and monetary health data as attention is a particularly data intensive and sensitive business. The unfortunate side of the sturdy knowledge flows is that the inherent downside of the misuse of knowledge, speech act of counselling and risk of privacy violations.
Medical confidentiality promotes the individual's medical autonomy, by sheltering those seeking virtuously polemic medical aid from outside criticism and interference with decisions.8 Medical privacy involves informational privacy (e.g., confidentiality, anonymity, secrecy and knowledge security); physical privacy (e.g., modesty and bodily integrity); memory privacy (e.g. intimate sharing of death, health problem and recovery); proprietary privacy (e.g., self-ownership and management over personal identifiers, genetic knowledge, and body tissues); and decisional privacy (e.g., autonomy and selection in medical decision-making).9 Justice prophet Dennis Warren and Justice prizefighter Brandeis outline privacy because the right "to be let

alone."10 the opposite definition given by Richard Rognehaugh is because the right of a personal to stay data concerning themselves from being disclosed to others; the claim of people to be coupled with, from police investigation or interference from alternative people, organizations or the government.11 data of a patient ought to be free to others solely with the patient's permission or allowed by law. once a patient is unable to try to to thus attributable to age, mental incapacity the selections concerning data sharing ought to be created by the personal representative or trustee of the patient. data shared as a results of clinical interaction is considered confidential and should be protected. {the information|the knowledge|the knowledge} will take varied forms (including identification data, diagnoses, treatment and progress notes, and laboratory results) and might be hold on in multiple media (e.g., paper, video, electronic files). data

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7 Mishra, N., Parker, L., Nimgaonkar, V., & Deshpande, S. (2008). Privacy and the Right to Information Act, 2005. Indian Journal of Medical Ethics, 5(4), 158-161.

8 Allen, A. (2011). Privacy and Medicine. in E. N. Zalta (Ed.), The Stanford Encyclopedia of Philosophy (2011st ed.). Retrieved from http://plato.stanford.edu/archives/spr2011/entries/privacy-medicine/.

9 Ibid.

10 Warren SD, Brandeis LD. The right to privacy. Harv Law Rev. 1890;4:193.

11 Rognehaugh R. The Health Information Technology Dictionary. Gaithersburg, MD: Aspen; 1999. p. 125.

12 Rinehart-Thompson LA, Harman LB. Privacy and confidentiality. In: Harman LB, editor. Ethical Challenges in the Management of Health Information. 2nd ed. Sudbury, MA: Jones and Bartlett; 2006. p. 53.

from that the identity of the patient can't be observed as an example, the amount of patients with breast cancer in a very government hospital, isn't during this class.13

Patients typically perceive that data concerning them needs to be shared among the care team to supply their care. however it's not continually clear to patients that others UN agency support the supply of care may additionally have to be compelled to have access to their personal data. And patients might not remember of disclosures to others for functions aside from their care, like service designing or medical analysis. you want to inform patients concerning disclosures for functions they might not moderately expect, or make certain they need already received data concerning such disclosures.

The read that protective patient confidentiality has ethical price however not absolute ethical price has been wide accepted since a minimum of the time of the traditional Greeks. The existence of the duty is an element of the Hippocratic Oath:

"Whatsoever things I see or hear regarding the lifetime of men, in my group action on the sick or maybe with the exception of there from, that ought to not be noised abroad, i'll keep silence on that reckoning such things to be as sacred as secrets."

That duty is reiterated within the Declaration of Geneva, which needs doctors to "respect the secrets that square measure confided . . . even once the patient has died".14 Neither of those instruments is known as imposing associate degree absolute duty.15

Privacy violations within the care sector that stem from policy and implementation gaps include: speech act of non-public health data to 3rd parties while not consent, inadequate notification to a tolerant a knowledge breach, unlimited or superfluous assortment of non-public health knowledge, assortment of non-public health knowledge that's not correct or relevant, the aim of assembling knowledge isn't nominal, refusal to supply medical records upon request by consumer, provision of non-public health knowledge to public health, research, and industrial uses while not de-identification of knowledge and improper security standards, storage and disposal. The speech act of non-public health data has the potential to be embarrassing, stigmatizing or discriminatory. what is more, varied merchandise like employment, life, and medical insurance, may well be placed in danger if the flow of medical data weren't restricted.16

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13 Rinehart-Thompson LA, Harman LB. Ethical Challenges in the Management of Health Information. 2nd ed. Sudbury, MA: Jones and Bartlett; 2006. Privacy and confidentiality; p. 54. Chapter 3.

14 The Declaration of Geneva was first adopted by the World Medical Association in 1948. It was last amended by the General Assembly in 2006.

15 See also art. 10 of the European Convention on Human Rights and Biomedicine.

We have already seen that every one the main ethical theories can insist that the confidentiality of data disclosed to a doctor or alternative health care provider ought to usually be determined. There is, nevertheless, a divergence of views on the precise moral justification and performance of the obligation of confidence.17 completely different|completely different} ethical theories can target different goals and edges protected by restraining the speech act of data divulged by a patient. Utilitarian's can target the possible profit to the utility balance. Respecting confidentiality can usually maximise utility, as a result of it's possible to encourage patients to be open with their doctor and to hunt medical help within the initial place. Duty primarily {based} and rights- based theories can target individual rights and interests, like those associated with privacy and autonomy. Virtue theories can target the virtues, like trait and confidentiality. several of those moral issues square measure broader than confidentiality intrinsically. protective autonomy interests within the shaping of one's life decisions, as an example, needs quite the power to regulate UN agency is aware of what concerning one's personal affairs. a number of these moral issues square measure justifications for maintaining confidentiality et al. square measure justifications for safeguarding medical data from more dissemination or misuse.

English law reflects the tensions displayed by totally different moral theories. we have a tendency to shall see that varied options may believably be viewed as appealing to the larger smart (e.g. the notion of the general public interest), individual rights and interests (e.g. the correct to privacy), and / or virtues (e.g. the notion of unconsciencability outlined by relevance the conscience of the person confided in). decoding English law by relevance a coherent underlying moral framework so presents a challenge. what's clear is that it adopts a robust presumption in favour of confidentiality with exceptions that involve a leveling exercise.

2.2.1 The Common Law Duty of Confidentiality

A breach of confidence can sometimes found an action in contract or the tort of negligence. To found an action in contract, the obligation of confidence would need to form an express or implied contractual term. An employee, for example, has a contractual duty of confidence whendealing with the sensitive business information of his employer. Only private patients, A breach of confidence will typically found associate degree action in contract or the civil wrong of negligence. To found associate degree action in contract, the requirement of confidence would wish to make associate degree categorical or silent written agreement term. associate degree worker, as an example, incorporates a written agreement duty of confidence once coping with the sensitive business data of his leader. solely non-public patients,however, enter into a contract with their doctor.18

16 Nissenbaum, H. (2004). Privacy as Contextual Integrity. Washington Law Review, 79(1), 101-139.

17 See Montgomery 2002, 253-254.

To found associate degree action in negligence, the requirement of confidence would wish to be a part of the duty of care, which should are broken and thereby caused unjust injury. However, the discharge of patient info, contrary to the behaviour of an affordable doctor, won't sometimes cause injury to the patient that's usually unjust injury in negligence. Most patients can suffer embarrassment or a sense of being profaned. AN action for breach of confidence can even be brought while not the
need to satisfy the strict necessities of contract or negligence. nineteen Such AN action is best characterized as single, etymologizing from the law of equity.
The traditional formulation for the action for breach of confidence was ordered down by Megarry J. in Coco v. Clark:
"First, the knowledge itself . . . should have the mandatory quality of confidence concerning it. Secondly, that info should are imparted in circumstances mercantilism AN obligation of confidence. Thirdly, there should be AN unauthorised use of that info to
the harm of the party human action it."20
In the 1st breach of confidence case to achieve the House of Lords, typically remarked because the Spycatcher case, Lord Goff expressed that:
"a duty of confidence arises once direction involves the data of someone (the confidant) in circumstances wherever he has notice, or is control to possess in agreement, that the knowledge is confidential, with the impact that it'd be simply all told the circumstances
that he ought to be precluded from revealing the knowledge to others."21
According to this approach, a requirement of confidence arises whenever the person receiving info is aware of, or need to recognize, that it's confidential. expressed within the abstract, this is often each imprecise and circular. It does, however, indicate that what matters is that the nature of the knowledge and therefore the circumstances of its acquisition. Lord Goff went on to mention that to be confidential, the knowledge should not be within the "public domain" and should not be "useless" or "trivia".22

18 See Reynolds v. Health First Medical Group [2000] Lloyd's Rep. Med. 240, applying Pfizer Corporation v.
Ministry of Health [1965] A.C. 512.

19 See e.g. Saltman Engineering v. Campbell Engineering [1963] 3 All ER. 413; AG v. Guardian Newspapers (No.2) [1990] 1 A.C. 109; and Ashworth Hospital Authority v. MGN [2002] UKHL 29.

20 Coco v. Clark [1968] F.S.R. 415 at 419. These criteria reflected earlier cases such as Prince Albert v. Strange (1849) 41 ER. 1171.

21 AG v. Guardian Newspapers (No.2) [1990] l A.C. 109 at 281.

22 [1990] 1 A.C. 109 at 282.

Other cases indicate that non-public and intimate info can qualify as
with respect to the circumstances of acquisition, Lord Keith cited the doctor-patient relationship as a well-established example of a relationship which will
give rise to AN obligation of confidence24 and alternative cases have control that this additionally applies to
other health professionals.25 in brief, the law of confidentiality without ambiguity protects the medical info of patients. Indeed, as we have a tendency to shall see, the duty of confidence is to be taken wide to administer impact to the art.8 Convention right to "private and family life".

Whether it's necessary for claimants to suffer a harm from the speech act of their direction was moot for a few time. harm was the third of Megarry J.'s three
requirements, however this issue was left open by the House of Lords within the Spycatcher case. 26 Subsequent cases demonstrate that it's not sometimes troublesome for the courts to search out a harm. 27 In Re C, as an example, the Court of charm accepted that the kid in question would continually stay blind to her condition however declared that speech act of her identity was possible to
adversely have an effect on the power of her carers to worry for her.28 In reference to medical info, it's currently usually accepted that the mere truth of speech act can live up to.29
It is typically same that the principal justification for respecting patient confidentiality is that the public interest. As Lord Goff place it within the Spycatcher case:
"there is such a public interest within the maintenance of confidences, that the law can give remedies for his or her protection".30
His Lordship reiterated this later in his judgment and noted that the public interest also providedthe principal legal justification for disclosing confidential information: "that public His Lordship reiterated this later in his judgment and noted that the general public interest additionally provided the principal legal justification for revealing confidential information: "that public interest could also be outweighed by another countervailing public interest that favours disclosure".31

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23 See e.g. Stephens v. Avery [1988] Ch. 449 (where information relating to sexual conduct of a lesbian nature was held to be confidential information).

24 [1990] 1 A.C. 109 at 255. This had been established in earlier cases: see e.g. Hunter v. Mann [1974] Q. B.
767 esp. at 772.

25 Ashworth Hospital Authority v. MGN [2002] UKHL 29.

26 [1990] 1 A.C. 109 at 255-256 (Lord Keith suggested that detriment might not be required), at 281-282 (Lord Goff left the issue open), and at 270 (Lord Griffiths considered detriment to be required).

27 See e.g. X Health Authority v. Y [1988] 2 All ER. 648 at 657-658 (Rose J. considered detriment to be unnecessary but found it anyway) and Campbell v. GMC [2002] EWHC 499 at para.40 (Morland J. easily found a detriment and this issue was not even addressed on appeal).

28 Re C (A Minor) (Wardship: Medical Treatment) (No. 2) [1990] Pam. 39 at 47-48 (Lord Donaldson), at 51 (Balcombe L.J.), and at 54-55 (Nicholls L.J.).

29 Cornelius v. De Taranto [2001] E.M.L.R. 12 at para.72 (confirmed without addressing this point by the Court of Appeal: [2001] EWCA Civ 1511]); R. v. Department of Health Ex p. Source Informatics [1999] 4 All ER. 185 (overturned, but the Court of Appeal sidestepped this point: [2001] QB. 424 at para.35); and Black v. The Information Commissioner (2007) 98 B.M.L.R. 1 at paras 14-15 (holding that detriment was not a necessary ingredient in relation to the disclosure of medical information).

30 AG v. Guardian [1990] 1 AC. 109 at 281.

2.2.2 **Age for Right to Confidentiality-**

The age at that the 'Right to Confidentiality' begins is nevertheless to be outlined by either the statute or the courts. as an example, the problem of confidentiality arises once a 16-year-old lady needs to grasp concerning the contraceptive procedures. below this legal provisions, it's unclear whether or not a tending skilled ought to inform the oldsters or respect the correct to confidentiality of the patient. MTP will be done if the gestation is alleged by the pregnant lady to possess been caused by rape, since the anguish caused by such gestation is likely to represent a grave injury to the mental state of the pregnant lady. In such things, either the consent of the girl if she is >18 years or the consent of the parents/ guardian if she is <18 years is obtained (Sections three (2) (i) and four (a) of the MTP Act, 1971). Also, in keeping with the MTP laws, 2003 (Section 6), the admission register recording the name and alternative particulars of the pregnant lady United Nations agency undergoes termination could be a confidential document and therefore the info contained in this shouldn't be disclosed to anyone aside from those licensed by the laws. However, the Protection of youngsters from Sexual Offences Act, two012 (Sections 2 (1) (d), nineteen (1) and twenty one (1)) and therefore the legal code modification Act, 2013 (Criminal Procedure Code Section 357C and IPC Section 375) criminalizes sex below eighteen years aged, although it's consensual; thereby it's likely that gestation could be a results of rape—a criminal offence reportable to the police. Further, below Section 202 of the IPC, it's the duty of someone to speak any criminal offence (such as rape) that he/she involves recognize of to the law-enforcing authority. Such contradicting statutory provisions leave tending professionals in an exceedingly quandary whether or not a gestation below eighteen years could be a reportable offence or not. Therefore, a holistic approach that addresses the issues of tending professionals, safeguards the rights of a minor lady to bear safe and legal MTP similarly as her right to confidentiality is required, lest this state of affairs
drive pregnant minor ladies to the unsafe services of quacks.32

31 [1990] 1 AC. 109 at 281, 282.

32 www.researchgate.net, 1 Dec. 2019, 10:00 p.m.

2.3 CONSENT-

In India, the doctor–patient relationship is ruled a lot of by trust wherever the doctor is that the authoritative person. Therefore, the good thing about consent ne'er reaches all patients in traditional practice. Also, an oversized section of the population of India is unfit by illiteracy and poorness, and remains outside the orbit of medical services rendered by qualified physicians of recognized medical systems. For them the problem of getting consent becomes inconsequential. This reality was recognized by the Supreme Court
of India in Samira Kohli v. Dr Prabha Manchanda33 during which the judgment declared that in India, a majority of voters requiring treatment and treatment fall below the poverty level. Most of them area unit illiterate or semiliterate. they can't comprehend medical terms, ideas and treatment procedures. they can't perceive the functions of assorted organs or the impact of removal of such organs. they are doing not have access to effective however expensive diagnostic procedures. Poor patients lying within the corridors of hospitals when admission for wish of beds or patients watching for days on the edge for Associate in Nursing admission or a mere examination may be a common sight. For them, any treatment with regard to rough and prepared diagnosing supported their outward symptoms and doctor's expertise or intuition is suitable and welcome goodbye because it is free or cheap; and regardless of the doctor decides as being in their interest is typically unquestioningly accepted. they're a passive, ignorant and uninvolved participant in treatment procedures. The poor and destitute face a hostile medical environment— inadequacy within the variety of hospitals and beds, non-availability of adequate treatment facilities, lack of qualitative treatment, corruption, insensitiveness and apathy. several poor patients with serious ailments (for instance, patients with heart diseases and cancers) got to sit up for months for his or her flip even for diagnosing, and thanks to restricted treatment facilities, several die even before their flip comes for treatment. What selection do these poor patients have? For them, any treatment of no matter degree may be a boon or a favour. the fact is that for a huge majority in India, the construct of consent or any kind of consent, and selection in treatment, has very little which means or connectedness.34

33 (2008) 2SCC 1, Para 26.

34 Karunakaran Mathiharan, Law on Consent and Confidentiality in India: A need for clarity, The National Medical Journal of India (Dec.1 2019, 10:00 p.m.) https://www.researchgate.net/publication/267511653_Law_on_consent_and_confidentiality_in_India_A_need_for_clarity.

2.3.1 **Consent to Communicate Information**-

Obtaining the patient's consent is that the most evident method of communication info concerning a patient's medieval condition to others while not attracting legal sanction. As Kennedy and Grubb properly indicate, the existence of consent isn't Associate in Nursing exception to the rule of confidence; it merely means the knowledge isn't confidential (Kennedy and Grubb, Medical law, 2nd ed. (London: Butterworths, 1994, p. 644).

For there to be consent as a matter of ethics likewise as law, it must be as well-read as doable and additionally voluntary. As already indicated, the patient consulting the doctor is during a vulnerable position. How many, on having a pre-operative examination in hospital would refuse the MD WHO asks 'You don't mind if these fifteen Pine Tree Statedical students watch me examine you, do you?' the case is fraught with potential anxiety for the patient and ripe for seldom- questioned breaches of medical confidence. Medical law during this instance ought to give for recognition of the strain of this example and need a precise sort of request to unharness the guidance. One would for sure feel a lot of au fait wherever the shape of question demanded at law to be one thing like, 'These area unit medical students. As a part of their coaching they have to check this type of pre-operative examination. i want your consent for that to happen, but
you needn't provides it if you are feeling uncomfortable. Do u understand?'35

Perhaps the foremost easy instance of permissible speech act of patient info is wherever the patient unambiguously consents to the speech act. speech act at intervals parameters of a sound consent won't breach the duty of confidence, as a result of the patient's consent operates as a discharge of the duty.

This is evident from Associate in Nursing early case during which a husband and married woman had, within the course of divorce proceedings, written to their doctor to request that he disclose info associated with her
venereal unwellness.36 Consent to the speech act of one's medical info doesn't sometimes raise the spectre of autonomous self-harm and thus tends to not evoke the division over whether or not there area unit direct duties to oneself. info is solely not confidential or non-public wherever the topic of that info doesn't regard it intrinsically the subject's consent permits speech act at intervals the parameters of that consent in each law and ethical theory.

35 Supra Note 6.

36 C v. C [1946] 1 All E.R. 562.

2.2.4 Disclosures for which express consent should be sought –

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As a general rule, you must look for a patient's categorical consent before revealing distinctive info

purposes aside from the availability of their care or native clinical audit, like audit and Insurance or edges claim. If you're asked to supply info to 3rd parties, like a patient's insurance company or leader or a section or workplace accessing a claimant's entitlements to edges, either following and examination or from existing records, you should:

(a) be glad that the patient has decent info concerning the scope, purpose and sure consequences of the examination and speech act, and also the undeniable fact that relevant info can't be concelaed or withheld.

(b) obtain or have seen written consent to the speech act from the patient or someone properly authorised to act on the patient's behalf; you will settle for Associate in Nursing insurance from and officer of a section or agency or a registered professional performing on their behalf that the patient or someone properly authorised to act on their behalf has consented.

(c) only disclose factual info you'll substantiate, bestowed in Associate in Nursing unbiased manner, relevant to the request; thus you must not sometimes disclose the entire record, though it's going to be relevant to some edges paid by government departments and to alternative assessments of patient's title to pensions or alternative health-related edges, and

(d) offer to point out your patient, or provide them a replica of, any report you write of them for employment or insurance functions before it's sent, unless:

(i)They have already indicated they are doing not would like to envision it

(ii) speech act would be seemingly to cause serious damage to the patient or anyone else

(iii) disclosure would be seemingly to reveal data concerning another one that doesn't consent.

If a patient refuses consent, or if it's not practicable to urge their consent, data will still be disclosed if it's needed by law or is even within the public interest.

- **Circumstances in which patients may give implied consent to disclosure -**

(Sharing data among the tending team or with others providing care)

Most patients perceive and settle for that data should be shared among the tending team so as to produce their care. you ought to make certain data is instantly accessible to patients explaining that, unless they object, personal data concerning them are going to be shared among the tending team, as well as body and alternative employees WHO support the availability of their care.

This data is provided in leaflets, posters, on websites, and face to face and may be tailored to patients' known desires as so much as practicable. Posters can be of very little help to patients with sight impairment or WHO don't scan English, for instance. In reviewing the data provided to patients, you ought to {consider|think concerning|contemplate|take into account} whether or not patients would be stunned to find out about however their data is being employed and disclosed.

You must respect the desires of any patient WHO objects to explicit data being shared among the tending team or with others providing care, unless speech act would be even within the public interest. If a patient objects to a speech act that you just take into account essential to the availability of safe care, you ought to justify that you just cannot refer them or otherwise

organize for his or her treatment while not conjointly revealing that data.

You must make certain that anyone you disclose personal data to understands that you just area unit giving it to them in confidence, that they need to respect. All employees members receiving personal data so as to produce or support care area unit sure by a responsibility of confidence, whether or not or not they need written agreement or skilled obligations to guard confidentiality.

Circumstances could arise within which a patient can not be privy concerning the speech act of knowledge, for instance in a very medical emergency. In such a case you ought to pass relevant data promptly to those providing the patient‘s care. If and once the patient is capable of understanding, you ought to inform them however their personal data was

disclosed if it absolutely was in a very approach they might not moderately expect.37

Unpacking consent-

Addressing consent as a justification for speech act needs some unpacking of the categories of situations wherever, conceptually, consent may well be moderately taken to possess been given.38 Consent is, in essence, a state of mind that's probably signalled in many various ways in which. Consent may even be taken to possess been signalled once the patient isn't really willing, as a result of the signalling individual has deliberately or unknowingly misled or the individual deciphering the signals has deliberately or unknowingly misread them.

37 Blackstone’s: Statutes on Medical Law, 401-410 (Edited by Anne E. Morris and Michael A. Jones, 7th Ed., Oxford University Press, 2011).

38 See Beyleveld and Histed 1999, 75 for distinctions between “implicit”, “implied”, “presumed”, and “imputed” consent.

When could a doctor moderately take the patient to be willing thus on think about that consent as a justification for revealing information? the foremost simple scenario is wherever the patient seems to expressly signal consent by (written or spoken) words of agreement or by conduct such as words of agreement (such because the unerect of the head). In such things the doctor may well be same to be looking forward to the patient's categorical consent. a small variation is conduct that seems to signal consent within the explicit context in question however wouldn't in alternative contexts. A patient might moderately be taken as signalling consent to AN injection by holding out AN arm in response to the doctor's recommendation of a tetanus injection, although holding out AN arm wouldn't indicate consent to AN injection in several alternative contexts.39 equally, a patient might moderately be taken to be signalling consent to the speech act of check leads to front of a partner if these results area unit requested whereas they're Sat along in a very doctor's surgery. In such things the doctor may well be same to be looking forward to the patient's implicit consent.

Where a patient consents to at least one activity, consent for an additional may well be same to be inexplicit wherever that alternative could be a necessary suggests that of fulfilling the aim that categorical consent has be obtained and therefore the patient within reason expected to remember of this affiliation. wherever a patient agrees to possess AN X-ray at a doctor's suggestion, for instance, consent to speech act of any relevant medical data to the specialist might moderately be inexplicit. (A patient WHO seeks hospital treatment can sometimes be treated by a team and will equally be moderately taken to possess impliedly consented to speech act to all or any members of that team for the needs of treating him.) If it's seemingly that the patient isn't tuned in to the necessity for the extra activity/ speech act, then the justification for playacting it can not be the patient's consent. If the law were to treat this as AN instance of consent, this may got to get on the premise of a legal fiction. A legal fiction would even have to be relied on in most circumstances wherever the patient has given no signal in the least.

To impute consent within the absence of any reason for thinking that the patient has really consented is to think about a justification apart from consent cloaked within the language of consent. within the absence of case law directly on this time, it's troublesome to take care once the law can allow reliance on fictional consent as if it were real consent.40

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39 Cf. O'Brien v. Cunard (1891) 28 N.E. 266.

40 Shaun D. Pattinson, Medical Law and Ethics, 199-240 (3rd Ed., Sweet and Maxwell, 2011).

Explicit consent is maybe the foremost obvious approach by that a doctor is eased of the duty of confidentiality. the problem becomes a lot of contentious within the event that it's alleged that a patient has given implied consent to disclosure.
Many would usually settle for that medical info are going to be shared at intervals the health-care team though it's smart follow to spotlight this chance with patients, notably if diagnosable info is being shared. The patient's understanding of the implications need to be checked and this is often notably apt wherever a patient could have at the start given consent for revealing and after withdraws this, or contrariwise.
If a patient undergoes a medical checkup on behalf of a 3rd party, as an example, for insurance functions or for employment, then it's a moot purpose on whether or not there's tacit consent for revealing of the report to the leader. In Kapadia v. London Borough
of Lambeth41, this issue was thought of by the Court of attractiveness and dicta provides that the report ought to be 'disclosed by the doctor to the employers. No more consent was needed from the applicant. By willing to being examined on behalf of the employers the applicant was willing to the revealing to the employers of a report ensuing from that examination'. whereas this most definitely represents one approach, an alternate perspective is that the doctor United Nations agency discloses such info has broken the duty of confidentiality, if not in law then definitely in terms of skilled ethics and will so be subject to disciplinary action by the medical regulator. In these specific circumstances, revealing of data to the leader that's directly associated with the impact of labor upon their health or the impact of health upon the geographic point may well be relevant, however revealing of alternative medical info may well be terribly onerous to justify.

- **PERMITTED DISCLOSURE-**

  - **Disclosures in the public interest-**

There is a transparent public smart in having a confidential medical service. the actual fact that folks area unit inspired to hunt recommendation and treatment, as well as for communicable diseases, edges society as an entire furthermore because the individual. Confidential treatment is recognised in law as being within the public interest. However, there may also be a public interest in revealing information: to guard people or society from risks of great damage, like serious communicable diseases or serious crime; or to change medical analysis, education or alternative secondary uses of data that may profit society over time.
Personal info could, therefore, be disclosed within the public interest, while not patients' consent, and in exceptional cases wherever patients have withheld consent, if the advantages to a personal or to society of the revealing outweigh each the general public and also the patient's interest to keep the data confidential. you need to weigh the damages that area unit probably to arise from non-disclosure of data against the attainable harm each to the patient, and to the
overall trust between doctors and patients, arising from the discharge of that info. 42
Before considering whether or not a revealing of private info would be even within the public interest, you need to be happy that diagnosable info is critical for the aim, or that it's not fairly practicable to anonymise or code it. In such cases, you must still get the patient's consent unless it's not practicable to try and do therefore, as an example because:

41 [2000] 57 BMLR 170.

(a) the patient isn't competent to relinquish consent, during which case you must consult the patient's welfare professional, court-appointed deputy, guardian or the patient's relatives, friends or carers.
(b) you have reason to believe that seeking consent would place you or others in danger of great damage
(c) seeking consent would be probably to undermine the aim of the revealing, as an example, by prejudicing the hindrance or detection of great crime, or
(d) action should be taken quickly, as an example, within the detection or management of outbreaks of some communicable diseases, and there's meager time to contact the patient.
You should inform the patient that a revealing are going to be created within the public interest, notwithstanding you have got not wanted consent, unless to try and do therefore is unfeasible, would place you or others in danger of great damage, or would prejudice the aim of the revealing. you need to document within the patient's record your reasons for revealing info while not consent and any steps you have got taken to hunt the patient's consent, to tell them concerning the revealing, or your reasons for not doing therefore.
The legal provisions with relevancy privacy, confidentiality and secrecy area unit typically outmoded by Public Interest issues. the proper to privacy, though recognized within the course of Indian jurisprudence and embodied at intervals domestic legislation is commonly overruled clear

when sweet-faced with things or instances that involve a bigger interest of a larger variety of individuals. This policy is to keep with India's policy goals as a financial aid state to assist within the implementation of its utilitarian ideals. This doesn't permit individual interest to at any purpose surpass the interest of the lots.

42 Supra note 40.

Epidemic Diseases Act, 1897

Implicit at intervals this formulation of this Act is that the assumption that within the case of infectious diseases, the proper to privacy, of infected people should settle to the preponderating interest of protective public health.43 this may be determined not solely from the Gothic of the Law however conjointly from its spirit. Thus, within the absolute positivist furthermore as a a lot of liberal interpretation, at the crux of the legislation lies the simple elementary covenant of the preservation of public health, even at the price of the privacy of a pick few individuals44.

- **Disclosures to protect others-**

Disclosure of private info a few patient while not consent is also even within the public interest if failure to disclose could expose others to a risk of death or serious damage. you must still get the patient's consent to revealing if practicable and think about any reasons given for refusal.
Such a state of affairs may arise, as an example, once a revealing would be probably to help within the hindrance, detection or prosecution of great crime, particularly crimes against the person.

> When victims of violence refuse police assistance, disclosure may still be justified if others remain at risk, for example, from someone who is prepared to use weapons, or from domestic violence when children or others may be at risk.
>
> If a patient's refusal to consent to disclosure leaves others exposed to a risk so serious that it outweighs the patient's and the public interest in maintaining confidentiality, or if it is not practicable or safe to seek the patient's consent, you should disclose information promptly to an appropriate person or authority. You should inform the patient before disclosing the information, if practicable and safe, even if you intend to disclose without their consent.

When victims of violence refuse police help, speech act should be even if others stay in danger, for instance, from somebody World Health Organization is ready to use weapons, or from force once youngsters or others is also in danger.
If a patient's refusal to consent to speech act leaves others exposed to a risk thus serious that it outweighs the patient's and therefore the public interest in maintaining confidentiality, or if it's not practicable or safe to hunt the patient's consent, you must disclose data promptly to associate applicable person or authority. you must inform the patient before revealing the knowledge, if practicable and safe, although you plan to disclose while not their consent.

You should participate in procedures found out to guard the general public from violent and sex offenders. you must co-operate with requests for relevant data regarding patients World Health Organization might create a risk of significant hurt to others.

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43 The Epidemic Diseases Act, 1897. s. 2.1.

44 The Epidemic Diseases Act, 1897, s. 2.2(b).

- **Disclosures when a patient may be a victim of neglect or abuse-**

If you think that a patient is also a victim of neglect or physical, sexual or emotional abuse, which they lack capability to consent to speech act, you need to offer data promptly to associate applicable accountable person or authority, if you think that the speech act is within the patient's best interests or necessary to guard others from a risk of significant hurt. If, for any reason, you think that speech act of knowledge isn't within the best interests of a neglected or abused patient, you must discuss the problems with associate knowledgeable about colleague. If you choose to not disclose data, you must document within the patient's record your discussions and therefore the reasons for deciding to not disclose. you must be ready to justify your call. Sharing data with a patient's partner, carers, relatives or friends.

You should establish with the patient what data they need you to share, who with, and in what circumstances. this can be significantly necessary if the patient has unsteady or diminished capability or is probably going to lose capability, even quickly. Early discussions of this nature will facilitate to avoid disclosures that patients would object to. they'll additionally facilitate to avoid misunderstandings with, or inflicting offence to, anyone the patient would need data to be shared with.

If anyone about to the patient desires to debate their issues regarding the patient's health, you must create it clear to them that, whereas it's not a breach of confidentiality to pay attention to their issues, you can't guarantee that you just won't tell the patient regarding the voice communication. you would possibly got to share with a patient data you've got received from others, for instance, if it's influenced your assessment and treatment of the patient. you must not refuse to pay attention to a patient's partner, carers or others on the idea of confidentiality. Their views or the knowledge they supply could be useful in your case of the patient. You will, though, got to {consider|think regarding|contemplate|take into account} whether or not your patient would think about you taking note of the issues of others about your patient's health or care to be a breach of trust, significantly if they need asked you to not hear explicit individuals.

- **Genetic and other shared information-**

Genetic and a few different data regarding your patient would possibly at identical time even be data regarding differents the patient shares genetic or other links with. The designation of associate sickness within the patient would possibly, for instance, purpose to the understanding or probability of identical sickness in a very cognate.

Most patients can pronto share data regarding their own health with their youngsters and different relatives, significantly if they're suggested that it would facilitate those relatives to:

(a) get prevention or different preventative treatments or interventions

(b) make use of multiplied police investigation or different investigations, or

(c) prepare for potential health issues.

However, a patient would possibly refuse to consent the speech act of knowledge that may profit others, for instance wherever family relationships have dampened, or if their natural youngsters are adopted. In these circumstances, speech act would possibly still be even within the public interest. If a patient refuses consent to speech act, you'll got to balance your duty to form the care of your patient your initial concern against your duty to assist shield the opposite person from serious hurt. If practicable, you must not disclose the patient's identity
in contacting and advising others if the risks they face.45

However, there area unit bound things wherever speech act of non-public health data is allowable, for example: 1) throughout referral, 2) once demanded by the court or by the police on a written requisition, 3) once demanded by insurance firms as provided by the Insurance Act once the patient has relinquished his rights on taking the insurance, and 4) once needed for specific provisions of compensation cases, consumer
protection cases, or for taxation authorities,46 5) illness registration, 6) disease investigations, 7) vaccination studies, or 8) drug adverse event coverage.47

45 Supra Note 37.

46 Thomas, J. (2009). Medical Records and Issues in Negligence, Indian Journal of Urology : IJU : Journal of the Urological Society of India, 25(3), 384-388. doi:10.4103/0970-1591.56208.

47 Plaza, J., & Fischbach, R. (n.d.). Current Issues in Research Ethics : Privacy and Confidentiality. Retrieved
December 5, 2011, from http://ccnmtl.columbia.edu/projects/cire/pac/foundation/index.html.

- **DISCLOSURES REQUIRED BY LAW-**

  - **Disclosures required by statute**

You must disclose data to satisfy a selected statutory demand, like notification of a proverbial or suspected case of bound infectious diseases. varied restrictive bodies have statutory powers to access patients' records as a part of their duties to research complaints, accidents or health professionals' fitness to practise. you must satisfy yourself that any speech act wanted is needed by law or may be even within the public interest. several restrictive bodies have codes of follow governing however they'll access and use personal data. Whenever practicable, you must inform patients regarding such disclosures, unless that may undermine the aim, although their consent isn't needed.

Patient records or different personal data is also needed by the GMC or different statutory regulators for associate investigation into a care professional's fitness to follow.

You should satisfy yourself that any revealing wanted is needed by law or is even within the public interest. several regulative bodies have codes of observe governing however they'll access and use personal data. Whenever practicable, you ought to inform patients regarding such disclosures, unless that might undermine the aim, even though their consent isn't needed.

Patient records or alternative personal data is also needed by the GMC or alternative statutory regulators for AN investigation into a aid professional's fitness to observe. If data is requested, however not needed by law, or if you're referring issues a couple of professional person to a regulation body, you must, if practicable, obtain the patients specific consent before revealing personal data. If a patient refuses to consent, or if it's not practicable to hunt their consent, you ought to contact the suitable regulative body, to assist you opt whether or not the revealing is even within the public interest.

  - **Disclosures to courts or in connection with litigation**

You must disclose data if ordered to try and do thus by a choose or leader of a court. you ought to object to the choose or the leader if tries square measure created to compel you to disclose what seems to you to be irrelevant data, like data a couple of patient's relative World Health Organization isn't concerned within the proceedings.

You must not disclose personal data to a 3rd party like a solicitor, officer or officer of a court while not the patient's specific consent, unless it's needed by law or will be even within the public interest.48

48 Supra Note 37.

- **RESEARCH AND OTHER SECONDARY USES-**

Research, medical specialty, public health police investigation, health service coming up with and education and coaching square measure among the vital secondary uses manufactured from patient data. Each of

these uses will serve vital public interests. for several secondary uses, it'll be enough and practicable to disclose solely anonymised or coded data. once distinctive data is required, or it's nor practicable to get rid of distinctive data, it'll usually be absolutely practicable to urge patients' specific consent. You may disclose distinctive data while not consent if it's needed by law, or if it is even within the public interest and it's either:

(a) necessary to use distinctive data, or

(b) not practicable to anonymise or code the knowledge and, in either case, not practicable to hunt consent (or efforts to hunt consent are unsuccessful).

In considering whether or not it's practicable to hunt consent you ought to understand of:

(a) the age of records and therefore the probably traceability of patients

(b) the range of records, and

(c) the risk of introducing bias attributable to an occasional response rate or as a result of explicit teams of patients refuse, or don't reply to, requests to use their data.

When considering whether or not the general public interest in disclosures for secondary uses outweighs patients' and therefore the public interest keep the knowledge confidential, you want to consider:

(a) the nature of the knowledge to be disclosed

(b) what use are manufactured from the knowledge

(c) how many folks can have access to the knowledge

(d) the confidentiality and security arrangements in situ to shield the knowledge from more revealing

(e) the recommendation of a Caldicott Guardian or similar professional advisor, World Health Organization isn't directly connected with the utilization that revealing is being thought-about, and

(f) the potential for distress or damage to patients.

It might not be practicable for the aid team, or those that sometimes support them, to anonymise or code data or to hunt patients' specific consent:

(a) for the revealing of distinctive data for vital secondary uses, or

(b) so that appropriate patients is recruited to clinical trials or alternative approved analysis comes.

If that's the case:

(a) identifiable data is also sent to a 'safe haven', wherever they exist and have the capabilities and square measure otherwise appropriate to method the knowledge (including anonymising or writing it) and to manage the revealing of knowledge for secondary uses or, if that's not practicable

b) the task of anonymising or writing the knowledge or seeking patients' consent to revealing is delegated to somebody incorporated into the aid team on a short lived basis and certain by legal and written agreement obligations of confidentiality.

You should solely disclose distinctive data for analysis if that analysis is approved by a research commission. you ought to alert analysis Ethics Committees to disclosures of distinctive data while not consent once applying for approval for research comes.49

- **Consent in Medical Research/Clinical Trials-**

The Declaration of Helsinki50 modified the moral reasoning of victimisation kith and kin for experimentation from consequentialist (or utilitarian) lines to deontological (duties and obligations). According to the port Declaration, it's the doctor's duty to confirm that each one patients square measure '…adequately hep of the aim, methods, anticipated edges, and potential hazards of the study and therefore the discomforts it should entail. He or she ought to be told that he or she is at liberty to abstain from participation within the study which he or she is unengaged to withdraw his or her consent to participate at any time. The doctor ought to then acquire the subject's freely- given consent, ideally in writing.'

Explaining each facet of the experimental medical care for the introduction of a replacement molecule or any such equally vital analysis to each potential human subject is troublesome. Most doctors concerned in trials of patients with HIV claim that they need obtained consent of the patients. However, it's attainable that this consent is also at the best be partially hep. With a majority of patients being economically and socially deprived, it's unclear whether or not the whole implications of a study square measure explained to them. there's attainable misuseof patients World Health Organization might conform to enroll in an exceedingly study while not a whole understanding of the analysis.

In a run of human benign tumor virus (HPV) immunizing agent meted out by the Program for applicable Technology in Health (PATH), a non-governmental organization, unitedly with the province and Gujarat governments and also the Indian Council of Medical analysis (ICMR), large-scale moral violations were reportable in getting consent of young women enclosed within the trial. The trial enclosed nearly twenty three,500 women within the age bracket of 10–14 years in Khammam district (Andhra Pradesh) and Vadodara (Gujarat). The consent forms were crammed with incomplete and possibly inaccurate knowledge, during a casual manner. In province, nearly 2800 consent forms were signed by a hostel warder or master, because the 'guardian' with the justification that oldsters weren't simply accessible. ought to the women are listed while not the fogeys consent because the treatment concerned wasn't aborning. there's no moral justification for a warder or master to act as a 'legally acceptable representative'. the very fact that lecturers vie a primary role in explaining associate degreed getting consent since students have reduced autonomy means the consent was obtained in an inappropriate manner, i.e. in a legally unreasonable method.52 In another recent episode in Indore, doctors were suspect of doing clinical trials for a international pharmaceutical company on patients while not getting their consent, that is necessary as per the rules of the Drug Controller General of India (DCGI). The doctors were additionally imagined to are given financial incentives and free foreign visits for doing the trials.53 The recently amended Schedule Y of the medicine associate degreed Cosmetics

Act states that once associate degree nonreader signs an consent to bear clinical trials, it ought to be obtained within the presence of associate degree impartial person. However, in observe, this may not be a hindrance to misuse gullible persons. In brief, the thought of consent specific to medical analysis and treatment remains alien to several medical researchers and practitioners and to immeasurable Indians.54

49 Ibid.

50 Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975, 35th WMA General Assembly, Venice, Italy, October 1983, 41st WMA General Assembly, Hong Kong, September 1989, 48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996, 52nd WMA General Assembly, Edinburgh, Scotland, October 2000, 53rd WMA General Assembly, Washington 2002, 55th WMA General Assembly, Tokyo 2004, 59th WMA General Assembly, Seoul, October 2008.

of patients who could agree to enrol in a study without a complete understanding of the research.[51]

In a clinical trial of human papilloma virus (HPV) vaccine carried out by the Program for Appropriate Technology in Health (PATH), a non-governmental organization, in collaboration with the Andhra Pradesh and Gujarat governments and the Indian Council of Medical Research (ICMR), large-scale ethical violations were reported in obtaining consent of young girls included in the trial. The trial included nearly 23,500 girls in the age group of 10–14 years in Khammam district (Andhra Pradesh) and Vadodara (Gujarat). The informed consent forms werefilled with incomplete and probably inaccurate data, in a casual manner. In Andhra Pradesh, nearly 2800 consent forms were signed by a hostel warden or headmaster, as the 'guardian' with the justification that parents were not easily reachable. Should the girls have been enrolled without the parents consent as the treatment involved was not emergent. There is no ethical justification for a warden or headmaster to act as a 'legally acceptable representative'. The fact that teachers played a primary role in explaining and obtaining consent since students have reduced autonomy means that the consent was obtained in an inappropriate manner, i.e. in a

legally untenable way.[52] In another recent episode in Indore, doctors were accused of doing clinical trials for a multinational drug company on patients without obtaining their consent, which is mandatory as per the guidelines of the Drug Controller General of India (DCGI). The doctors were also alleged to have been given monetary incentives and free foreign trips for

doing the trials.[53] The recently amended Schedule Y of the Drugs and Cosmetics Act states that when an illiterate person signs an informed consent to undergo clinical trials, it should be obtained in the presence of an impartial person. However, in practice, this will not be ahindrance to misuse gullible persons. In brief, the concept of informed consent specific to medical research and treatment is still alien to many medical researchers and practitioners and

to millions of Indians.[54]

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51 Bhandare N. HIV—red alert. The New Indian Express (Chennai Edition) 2000 21 May 2000: 2[Express Magazine].

52 A shockingly unethical trial [editorial]. Available at http://www.hindu.com/2011/05/16/stories/2011051650391000.htm (accessed on 1 July 2013): Dhar A. Final HPV enquiry report finds evidence of ethical violations. Available at http://www.indiaeveryday.in/fullnews-final-hpv-enquiry-report-finds-evidence-of-ethical-1005-2591112.htm (accessed on 1 July 2013).

53 Dhar A. Medical ethics violation to be made punishable offence. Available at http://www.thehindu.com/todays-paper/tp-national/article545280.ece (accessed on 1 July 2013).

54 Supra Note 34.

- **CONFIDENTIALITY AND THE LEGALLY INCOMPETENT-**

The obligation of confidence in reference to kids and incapacitated adults could be a very little additional complicated than for capacitated adults. First, if a requirement of confidence is to be owed to all or any kids and incapacitated adults, then it has to be supported on the character of the data alone. Some kids associate degreed incapacitated adults can merely not be able to type a relationship of confidentiality or operate with an expectation that info are unbroken secret. Secondly, any duty of confidence can ought to appreciate of the role of the patient's primary carer. The people underneath discussion here square measure people who square measure undergoing treatment or receiving recommendation, nonetheless don't seem to be regarded at law as having the flexibility to regulate the dissemination or otherwise of their confidential medical records. The candidates for management could also be the parent(s) of a minor, the person wrongfully selected as acting within the interests of a mentally incompetent adult or the doctor exploitation clinical judgment within the best interests of the patient. The later chapters on consent and psychological state can discuss very well the flexibility of the mentally incompetent typically to create selections concerning themselves, however a number of general points ought to be noted here.
The case of Gillick v. West metropolis and Wisbech space Health Authority55, whereas basically a matter of consent, has still enunciated a principle of general application to minors in medical law. wherever confidentiality is in issue, note the pressures that exist. the fogeys square measure naturally involved to understand what's happening to their kid. the kid desires to stay additional and additional secrets. the selection in Gillick was between a standing and a capability approach. The standing approach has the advantage of certainty. There would be one cut-off purpose. a baby underneath the age of sixteen wouldn't be regarded in law as competent to create selections concerning medical treatment. the choice read canvassed, and also the one that is accepted and permeates medical law because it relates to minors, is that the capability approach. a baby is competent to create selections on treatment severally of the desires of the fogeys. this could solely occur, however, wherever the kid is regarded, no matter his or her age, as capable of understanding the contents and implications of the alternatives which may be created. this is applicable equally to true wherever the parent or another requests or demands confidential medical info on the kid. this can be to not blind oneself to the conflicting pressures that may exist during this scenario. The welfare of the kid is of preponderant importance, and it might be anticipated that the doctor would base the assessment of understanding with respect to the welfare issue

55 (1986) AC 112, HL.

alongside the easy application of the Gillick formula. The doctor includes a duty to push the most effective interests of the kid. If there's proof of statutory offense, for instance, then there's the general public interest within the detection of crime and also the best interests of the child's mental and physical welfare and protection.

Building on this approach, Kennedy and Grubb have argued that it's "analytically preferable" to found the duty of confidentiality on the child's ability to make a confidential relationship or associate degree expectation that the data are unbroken secret.56 They argue that this approach, which might deny a requirement of confidence to kids UN agency square measure unable to know what secrecy entails, fits higher with the approach taken to capability to consent to treatment. each capability to consent and capability to request confidentiality would activate the child's ability to know what's entailed by the activity in question.

Where the incompetent adult worries it'll be discovered that there's not a parens patriae (really the court acting because the preserver of these UN agency cannot shield themselves) jurisdiction to permit for judicial say-so on info revealing. except for the psychological state legislation that exists at this time, there seems to be scant structure to organise a decision- creating method on cathartic info concerning the mentally incompetent adult.

There ar difficulties in medical law viewing this as a 'typical' bilateral doctor-patient relationship. The adult patient cannot in apply enter a relationship of confidence by mere reason of the incapacity. The matter nowadays is very impromptu. the event of case law on the sterilisation of the mentally incapacitated indicates a type of development, denoting another common law 'best interests of the patient' check, but one which, it'd be recommended, may be a but ideal guide. 57

The idea that the existence of a obligation of confidence is decided by the patient's capability is,

however, troublesome to reconcile with the case law even before Campbell v. MGN. fifty eight There had been a string of cases wherever injunctions were granted against the publication of the identities kidren|of youngsters|of kids} within which there's powerful dicta to the impact that a obligation of confidence is owed to Associate in Nursing incompetent child. In Re C, the Court of attractiveness nem con declared that a obligation of confidentiality was owed to a baby by all those caring for her.59 In another case, Dame

56 See Kennedy and Grubb 2000, 1077-1078.
57 Supra Note 6.
58 [2004] UKHL 22.
59 [1990] Pam. 39 at 48 (Lord Donaldson), at 52 (Balcombe L.J.) and at 54 (Nicholle L.J.).

Elizabeth Butler-Sloss created it clear that she had no reservations regarding the existence of a general duty of confidence owed to all or any children:
"Children, like adults, ar entitled to confidentiality in respect of sure areas of knowledge. Medical records ar the apparent example."60
In Re Z, the Court of attractiveness even recommended that in sure circumstances, a parent may well be certain by a obligation of confidence to their kid.61 None of those cases explained exactly why a duty of confidence is owed to Associate in Nursing incompetent kid.62 Since the duty protects all patients, any revealing has to be even within the public interest. Of course, a crucial variable within the application of the general public interest justification would got to be the child's capability. there's sure as shooting a compelling public interest justification for revealing data to the child's folks wherever the kid lacks capability,63 as parental consent would typically be required before the treatment may well be administered lawfully. wherever I kid will lawfully consent to treatment (i.e. is Gillick competent), the general public interest in revealing data to his folks is a smaller amount compelling.
The approach of the House of Lords within the Campbell case was, as already expressed, to link the art.8 right to privacy with the action for breach of confidence. it's well established in Convention jurisprudence that kids have a right to privacy below art. 8(1),64 thus any revealing of the child's medical data can ought to be even as necessary for the proportionate pursuit of a legitimate aim recognised by art.8(2).
The most moot things ar those wherever a toddler with capability to consent to treatment insists that the small print of her medical consultation on family planning or abortion ar unbroken from her folks. This was the terribly issue to arise for thought in R. (Axon) v. Secretary of State for Health.65 Over twenty years once Gillick, Mrs. axone sought-after to challenge Department of Health guidance.66 Mrs axone argued that the Department of Health steerage had perverted the law as expressed in Gillick. The duty of confidence owed to a toddler was, she argued, subject to the parent's responsibility for the welfare of their kid. consequently, health professionals were solely below Associate in Nursing obligation to take care of the boldness of a toddler below

16 United Nations agency sought-after recommendation or treatment on sexual matters (contraception, sexually transmitted infections, and abortion) wherever parental information "would or would possibly prejudice a child's physical or mental state in order that it's within the child's bests interests" to take care of the confidence.67 As Loughrey has identified, queries stay regarding extent of duties owed to children against their folks after they don't seem to be Gillick-competent.68 The position of incapacitated adults is analogous thereto of kids. In R. (S) v. Plymouth council, the Court of attractiveness recognised that incapacitated adults were owed a obligation of confidence and had a right to privacy below art.8.69 The human, S, was the mother of Associate in Nursing incapacitated adult and wanted to visualize the medical records of her kid. in step with Hale L.J.: "both at common law and below the Human Rights Act, a balance should be affected between the general public and personal interests in maintaining the confidentiality of this data and therefore the public and private interests in allowing, so requiring, it's revealing certainly functions."70 The court of attractiveness in agreement on these principles however was divided over the applying of this equalization exercise to the facts. the bulk dominated that the balance favoured revealing.

60 Venables v. NGN [2001] Pam. 430 at 469.
61 See e.g. Re Z [1997] Farm. 1 at 25 (Ward L.J. with whom the other judges agreed).
62 See Loughrey 2003.
63 Save in extreme circumstances, such as suspected child abuse.
64 See e.g. Gaskin v. United Kingdom (1990) 12 E.H.R.R. 36 and Glass v. UK [2004] 1 ELK 1019.
65 [2006] EWHC 372.
66 See DH 2004b.

Disclosures about patients who lack capacity to consent-

There is recommendation on assessing a patient's wit in our steerage Consent: patients and doctors creating selections along and within the Adults with Incapacity (Scotland) Act 2000 and wit Act 2005 codes of apply. there's no specific wit legislation for European country.
For recommendation in relevance kids and kids, see our steerage 0-18 years: steerage for all doctors. once creating selections regarding whether or not to disclose data a couple of patient United Nations agency lacks capability, you must:
(a) make the care of the patient your initial concern
(b) respect the patient's dignity and privacy, and
(c) support and encourage the patient to be concerned, as way as they require and ar ready, in selections regarding revealing of their personal data.
You must conjointly consider:

(a) whether the patient's lack of capability is permanent or temporary and, if temporary, whether or not the choice to disclose may fairly wait till they regain capability

(b) any proof of the patient's antecedently expressed preferences

(c) the views of anyone the patient asks you to consult, or United Nations agency has legal authority to form a choice on their behalf, or has been appointed to represent them

(d) the views of individuals on the brink of the patient on the patient's preferences, feelings, beliefs and values, and whether or not they contemplate the projected revealing to be within the patient's best interests, and

(e) what you and also the remainder of the aid team realize the patient's needs, feelings, beliefs and values.71

If a patient WHO lacks capability asks you to not disclose personal info concerning their condition or treatment, you must associate degreed} persuade them to permit an applicable person to be concerned within the consultation. If they refuse, and you're convinced that it's essential in their best interests, you will disclose relevant info to AN applicable person or authority. In such a case you must tell the patient before revealing the knowledge and, if applicable, request and punctiliously take into account the views of AN advocate or carer. you must document within the patient's record your discussions and also the reasons for deciding to disclose the knowledge.

You may have to be compelled to share personal info with a patient's relatives, friends or carers to modify you to assess the patient's best interests. however that doesn't mean they need a general right of access to the patient's records or to own extraneous info concerning, as an example, the patient's past aid. you must additionally share relevant personal info with anyone WHO is authorised to create choices on behalf of, or WHO is appointed to support
and represent, a mentally incapacitated patient.72

The duty of confidentiality extends to the adult WHO lacks capability and is protected by law. In R

(on the appliance of Stevens) v. Plymouth town Council73, a case set before implementation of the learning ability Act 2005, the court explicit that it absolutely was only too simple for professionals

to contemplate those that lacked capability as having no freelance interests, nevertheless the importance of the duty of confidentiality to such patients couldn't be overestimated. This

decision is currently increased by the learning ability Act 2005 and also the have to be compelled to act within the patient's best interests.

67 [2006] BWHC 372 at para.29.
68 See Loughrey 2008.
69 [2002] EWCA Civ 388 esp. at paras 49 and 50 (Hale L.J.).
70 [2002] EWCA Civ 388 at para.32.
71 Supra note

- **CONFIDENCE AND DEATH-**

A brief mention ought to be product of confidences that endure when death. Why? just because of the moral notion of respecting the memory of the deceased, however additionally as a result of medical revelations will damage the living. The declaration of Geneva, it'll be recalled, couldn't be clearer on the matter. Strangely, there's very little confidential concerning the death itself, as a result of the death certificate itself may be a public document. Mason and McCall Smith pertinently note the stigma of AIDS following victims to the grave. To be strictly correct on the death certificate, the doctor ought to properly indicate the reason behind death. If 'AIDS' is placed on the certificate, then ill-informed rumour would possibly well attach to living partners, friends and relatives. The key to the problem of death and confidentiality in medical law takes one back to the beginning: upon what's it based? If it's the reciprocity of the doctor-patient relationship, then that has ceased to exist. If it's the doctor's duty to society as a full,
then this 'public' duty would possibly embody a permanent duty of overall medical confidence.74 There ar many reasons why the duty to take care of confidentiality extends when death. it's within the interests of all patients to understand that the knowledge they disclose can stay confidential and such a rule is premised on the notion that it'll turn out the simplest consequences. Maintaining confidentiality additionally protects the interests of alternative teams like blood relatives and third parties since the discharge of counsel may result in
very real damage, a read maintained in Bluck v. the knowledge Commissioner75 and confirmed in Lewis v. Secretary of State for Health76. In Lewis the choose explicit that there was little question that knowledgeable obligation was owed by the doctor to take care of the patient's medical confidences when the patient's death. However, this obligation are often overridden within the public interest and also the duty of confidence must be balanced against what actually lies within the public interest.

74 Supra Note 6.
75 (2007) 98 BMLR 1.
76 [2008] EWHC 2196.

- **Disclosure after a patient's death-**

Your duty of confidentiality continues when a patient has died. whether or not and what personal info is also disclosed when a patient's death can rely upon the circumstances. If the patient had asked for info to stay confidential, you must typically respect their needs. If you're unaware of any directions from the patient, after you are considering requests for info you must take into account:
(a) Whether the revealing of knowledge is probably going to cause distress to, or be of profit to, the patient's partner or family
(b) whether the revealing will disclose info concerning the patient's family or anyone else
(c) Whether the knowledge is already knowledge or are often anonymized or coded, and
(d) the purpose of the revealing.

There ar circumstances during which you must disclose relevant info a few patient WHO has died, for example:
(a) to facilitate a medical examiner, procurator business or alternative similar officer with AN enquiry or fatality inquiry
(b) when revealing is needed by law, or is even within the public interest, like for education or analysis
(c) for National Confidential Inquiries or for native clinical audit
(d) on death certificates, that you want to complete honestly and totally
(e) for public health police work, during which case the knowledge ought to be anonymized or coded, unless that will defeat the aim
(f) when a parent asks for info concerning the circumstances and causes of a child's death
(g) when a partner, shut relative or friend asks for info concerning the circumstances of AN adult's death, and you have got no reason to believe that the patient would have objected to such a revealing, and
(h) when someone encompasses a right of access to records underneath any law competent.

Archived records about deceased patients stay subject to a obligation of confidentiality, though the potential for revealing info concerning, or inflicting distress to, surviving
relatives or damaging the public's trust can diminish over time.

> Imagine a woman from a devout Catholic family who wishes to have an abortion. She is anxious that her family never finds out, even after she dies. Imagine another patient who is currently being treated for cancer and who also fears that he might have contracted HIV. He is anxious that no one ever finds out that he had contracted HIV, if he has, because he fears that it will cause the small community from which he comes to stigmatise his whole family. In both scenarios the patients do not readily draw a distinction between disclosure of their medical information now or after their death. Fear of future disclosure could lead them to avoid complete openness with their doctor. In the HIV scenario, the patient might even avoid seeking further treatment for his cancer if he thought that his doctor would disclose information relating to his HIV status. A significant likelihood of posthumous disclosure could thereby lead these patients to suffer considerable distress and could undermine their confidence in the healthcare system. It is not difficult to see why the major moral theories should be concerned about maintaining the secrecy of patient information even after the

patient's death. Even if the dead themselves are not considered to have any interests-which is an issue on which different views are taken-posthumous confidentiality can protect important moral interests.

If further scenarios are needed to demonstrate the potential of posthumous disclosure to infringe patient's rights or expectations, produce significant disutility, or compromise important virtues. A Catholic woman who is anxious that her gynaecological information is not used for research into chemical contraceptives is unlikely to consider it relevant whether the research takes place before or after her death.[78] The point is that many of the ethical concerns that give rise to the ethical obligation to protect patient confidentiality continue to have force once the patient has died. It might be easier to justify posthumous disclosure than to justify disclosure during the patient's life time (because a living individual can be harmed directly), but it does not follow that posthumous disclosure is unproblematic.

Until recently, there was no case law addressing the question of whether a duty of confidence can be owed to, or in respect of, a patient who is now dead. Kennedy and Grubb had argued by analogy with the law of defamation (a dead person cannot sue for defamation)[79] that the common law of confidentiality does not apply to disclosures after a patient's death.[80] This analogy has a certain force: if posthumous defamatory statements do not give rise to a cause of action, why should posthumous statements of true medical facts? However, maintaining confidentiality arguably protects wider and more important interests than preventing defamatory statements. Medical confidentiality is intimately connected with maintaining confidence in the medical profession and healthcare system.

In **Lewis v. Secretary of State for Health**, the High Court was asked to consider the disclosure of the medical records of certain deceased patients to an inquiry into human

77 Supra Note 37.

78 This hypothetical scenario derives from Beyleveld and Histed 1999, 73-74, who use it in the context of anonymisation.

tissue analysis in UK nuclear facilities.[81] Both parties invited the High Court to authorise the relevant disclosure, but differed as to the source of the authority for doing so. Since the parties accepted that the duty of confidentiality of a doctor towards a patient continues after the patient's death, Foskett J. did not find it necessary to reach anything more than a prima facie conclusion, namely, that "it is arguable that the duty of confidentiality does survive the death of the patient".[82] This conclusion was reached taking into account the positionadopted by the relevant professional guidance, the general expectations of patients, and the likely consequences of holding otherwise.[83]

79 Law Reform (Miscellaneous Provisions) Act 1934 (as amended) s.1(1).

80 Kennedy and Grubb 2000, 1082. See also Law Commission 1981, para.4.107 and DH 2003d, 29. Cf. Toulson and Phipps 1996, para.13.17.

81 [2008] EWHC 2196.

82 [2008] EWHC 2196 at para.18.

83 [2008] EWHC 2196 at paras 19-31. Foskett J. also cited a decision of the Tribunals Service Information Tribunal that had reached the same conclusion: Bluck v. The Information Commissioner (2007) 98 B.M.L.R.

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CHAPTER-III

STATUTORY PROVISIONS

“The law and medicine should be very serious professions to undertake, should they not? People’s lives and fortunes depend on them.” - George Elliot

CHAPTER-III

STATUTORY PROVISIONS

3.1 THE EMBODIMENT OF PRIVACY REGULATION WITHIN DOMESTIC LEGISLATION-

THE EMBODIMENT OF PRIVACY REGULATION at intervals DOMESTIC LEGISLATION-
This section of the study associate degreealyses the viability of an approach that takes into consideration the efficaciousness of domestic legislation in control pracices concerning the privacy of people within the aid sector. This approach perceives the letter and spirit of the law because the foundational structure upon that internal practices, self-regulation and therefore the effective implementation of policy issues that aim to form an environment of effective privacy regulation take form, at intervals establishments that provide aid services. to the current impact, domestic legislation that has for the protection of a patient's privacy has been examined. The law has been any studied with reference to its tendency to percolate into the everyday practices, rules and pointers that non-public and government hospitals adhere to. The extent of its permeation into actual practice; in lightweight of its efficaciousness in fulfilling the perambulatory objectives of making certain safe and retiring practices, at intervals the construct of that a patient is allowed to recover and look for treatment, has additionally been examined.

The term 'Privacy' is employed in an exceedingly multitude of domestic legislations primarily within the context of the inspiration of the fiduciary relationship between a doctor and a patient. This fiduciary relationship emanates from an inexpensive expectation of mutual trust between the doctor and his patients and is established through the Indian Medical Council Act of 1952, specifically section 20(A) of the Act that lays down the code of ethics that a doctor should adhere to in the least times. Privacy at intervals the aid sector includes variety of aspects as well as however not restricted to informational privacy (e.g., confidentiality, anonymity, secrecy and information security); physical privacy (e.g., modesty and bodily integrity); scientific theory privacy (e.g. intimate sharing of death, malady and recovery); proprietary privacy (e.g., self-ownership and management over personal identifiers, genetic information, and body tissues); and decisional privacy (e.g., autonomy and selection in medical decision-making).

3.1.1 Consent vis-a-vis Indian Law

An invasive therapeutic or investigatory procedure while not consent is technically electric battery (trespass) which may be tried either beneath criminal or wrongful conduct (civil) law. once it's a criminal offence, the indictments area unit framed beneath the legal code and once compensation is concerned, wrongful conduct law is employed. The statutory sections associated with sophisticated consent-

Indian Penal Code, 1860

- **Section-87**. Act not intended and not known to be likely to cause Death or Grievous Hurt, done by consent Nothing which is not intended to cause death, or grievous hurt, and which is not known by the doer to be likely to cause death or grievous hurt, is an offence by reason of any harm which it may cause, or be intended by the doer to cause, to any person, above eighteen years of age, who has given consent, whether express or implied, to suffer that harm; or by reason of any harm which it may be known by the doer to be likely to cause to any such person who has consented to take the risk of that harm.
- **Section-89**. Act done in Good Faith for Benefit of Child or Insane Person, by or by Consent of Guardian.

  Nothing which is done in good faith for the benefit of a person under twelve years of age, or of unsound mind, by or by consent, either express or implied, of the guardian or other person having lawful charge of that person, is an offence by reason of any harm which it may cause, or be intended by the doer to cause or be known by the doer to be likely to cause to that person.
- **Section-92**. Act done in Good Faith for Benefit of a Person without Consent
  Nothing is an offence by reason of any harm which it may cause to a person for whose benefit it is done in good faith, even without that person's consent, if the circumstances are such that it is impossible for that person to signify consent, or if that person is incapable of giving consent, and has no guardian or other person in lawful charge of him from whom it is possible to obtain consent in time for the thing to be done with benefit.
- **Section-202**. Intentional omission to give information of offence by person bound to inform

  Intentional omission to give information of offence by person bound to inform.— Whoever, knowing or having reason to believe that an offence has been committed,

intentionally omits to give any information respecting that offence which he is legally bound to give, shall be punished with imprisonment of either description fora term which may extend to six months, or with fine, or with both.

The Criminal Law (Amendment) Act, 2013, (Amendments to Indian Penal Code, 1860)

- **Section-375**. Rape

  Sixthly. With or without her consent, whom she is under eighteen years of age

  Exception 2—Sexual intercourse by a man with his own wife, the wife not being under fifteen years of age, is not rape.

The Criminal Law (Amendment) Act, 2013, (Amendments to Criminal Procedure Code, 1973)

- **Section-357C**. All hospitals, public or private, whether run by the Central Government, the State Government, local bodies or any other person, shall immediately, provide the first-aid or medical treatment, free of cost, to the victims of any offence covered under section 326A, 376, 376A, 376B, 376C, 376D or section 376E of the Indian Penal Code, and shall immediately inform the police of such incident.

Indian Contract Act, 1872

- **Section-11**. Who are competent to contract. Every person is competent to contract who is of the age of majority according to the law to which he is subject and who is of sound mind, and is not disqualified from contracting by any law to which he is subject.

The Indian Majority Act, 1875

- **Section-3**. Age of majority of persons domiciled in India.

  (1) Every person domiciled in India shall attain the age of majority on his completing the age of eighteen years and not before.

Medical Termination of Pregnancy Act, 1971

- **Section-3**. When Pregnancies may be terminated by registered medical practitioners.

  (2) (i) the continuance of the pregnancy would involve a risk to the life of the pregnant woman or of grave injury physical or mental health

Explanation one. - wherever any maternity is alleged by the pregnant lady to possess been caused by rape, the anguish caused by such maternity shall be likely to represent a grave injury to the psychological state of the pregnant lady.

(4) (a) No maternity of a lady, UN agency has not earned the age of eighteen years, or, who, having earned the age of eighteen years, may be a lunatic, shall be terminated except with the consent in writing of her guardian.

The absence of firm and unambiguous legal provisions concerning consent in regard to the medical treatment is mirrored within the following incident. In Nov 1993, once a 16-year-old woman eloped and got married, her father most popular a criticism with the police. (According to Indian law, if a lady underneath eighteen years elopes, the person with whom she elopes are often charged for the offence of seizure a minor woman.) The police copied the couple and therefore the boy was discharged on bail by a Judicial judge whereas the woman was taken to the boy's house. On a habeas corpus petition filed by the daddy of the woman, the Madras tribunal directed the woman be sent to a shelter for girls. when a month, the woman was found to be pregnant and therefore the father filed another habeas corpus petition within the Madras tribunal seeking a direction for medical termination of his daughter's maternity. (As per provisions of the MTP Act, solely a lady higher than eighteen years will offer consent to endure abortion. however the worry of supportive the age isn't on the doctor.) The Division Bench of the Madras tribunal when taking note of the woman, UN agency determined on continued with the maternity, refused to order termination of the maternity.84

In one more incident, in Gregorian calendar month 1994, excision was done on sixteen people ladies during a state-run asylum at Pune upon the order of the authorities. the explanation mentioned was personal hygiene and protection from unwanted pregnancies. For those ladies UN agency had folks, the consent of the fogeys was obtained. This incident induced a nationwide protest within the media. The National Commission for girls referred the touch on the Medical Council of India (MCI) for its opinion. The MCI command that it had been AN unethical and inappropriate thanks to traumatize social evils or hygiene.85

84 News report. The Hindu (Chennai Edition), 24–25 November 1994.

85 Seshadri M. A question of dignity. The Hindu 6 March 1994; p. 5; News Report. The Hindu (Chennai Edition) 6 June 1994.

Medical Termination of Pregnancy Regulations, 2003

- **Section-6**. Admission Register not to be open to inspection.

The Admission Register shall be kept in the safe custody of the head of the hospital or owner of the approved place, or by any person authorized by such head or owner and saveas otherwise provided in sub-regulation (5) of regulation 4 shall not be open for inspection by any person except under the authority of law:

Provided that the registered medical practitioner on the application of an employed woman whose pregnancy has been terminated, grant a certificate for the purpose of enabling her to obtain leave from her employer; Provided further that any such employer shall not disclose this information to any other person.

The Protection of Children from Sexual Offences Act, 2012

- **Section-2**. (1) (d) 'child' means any person below the age of eighteen years
- **Section-19**. (1) Notwithstanding anything contained in the Code of Criminal Procedure, 1973, any person (including the child), who has apprehension that an offence under this Act is likely to be committed or has knowledge that such an offence has been committed, he shall provide such information to, (a) the Special Juvenile Police Unit; or (b) the local police.
- **Section-21**. (1) Any person who fails to report the commission of an offence under sub-section (1) of section 19 shall be punished with imprisonment of either description which may extend to six months or with fine or with both.[86]

3.1.2 Domestic Legislations

4 The following domestic legislations are studied and relevant provisions of the Act are accentuated so as to analyse their compliance with the fundamental principles of privacy as ordered get in the A.P Shah of Iran Committee report on Privacy.

86 Supra Note 34.

- **Mental Health Act, 1987**

The Provisions underneath the Act bearing on the protection of privacy of the patient are examined. The principles embodied inside the Act embody aspects of the Law that confirm

the nature and extent of oversight exercised by the relevant authorities over the gathering of data, the limitation on the gathering of knowledge and therefore the restrictions on the revelation of the info collected. The principle of oversight is embodied underneath the legislation inside the provisions that yield the scrutiny of records in medicine hospitals and nursing homes
only by officers approved by the authorities.87 The limitation on the gathering of data is obligatory by the scrutiny of living conditions by a specialist and 2 social employees ar on a monthly basis. this might embody analyzing the living condition of each patient and therefore the body processes of the insane asylum and/or medicine nursing
home.88 to boot, guests should maintain a book concerning their observations and remarks.89 Medical certificates is also issued by a doctor, containing info concerning the character and degree of the mental disturbance as reasons for the detention of an individual during a medicine
hospital or medicine rest home.90 Lastly, the revelation of private records of any facility underneath this Act by inspecting officers is prohibited.91

Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994[92]

The Act was instituted in lightweight of a current public interest thought of preventing feminine foeticide. However, it's imperative that the supply of the Act stay simply back of unnecessarily intrusive techniques associated don't violate the fundamental human demand of privacy in an inherently personal sphere. The procedure that a mother has got to follow so as to avail of pre-natal diagnostic testing is necessary consent older, abortion history and case history. These conditions need a girl to reveal sensitive data
concerning case history of retardation or physical deformities.93 A special concern for privacy and confidentiality ought to be exercised with regards to revelation of genetic data.94

87 The Mental Health Act, 1987, s. 13(1).

88 The Mental Health Act, 1987, s. 38.

89 The Mental Health Act, 1987, s. 40.

90 The Mental Health Act, 1987, s. 21(2).

91 The Mental Health Act, 1987, s. 13(1), Proviso.

92 Also see the: Pre-Conception and and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Rules, 1996.

93 Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, s. 4(3).

94 Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994, s. 4(2). Pre-natal diagnostic techniques shall be conducted for the purposes of detection of: chromosomal abnormalities, genetic metabolic diseases, haemoglobinopathies, sex-linked genetic diseases, congenital anomalies any other abnormalities or diseases as may be specified by the Central Supervisory Board.

- **Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 (Code of Ethics Regulations, 2002)**

The Medical Council of Republic of India (MCI) Code of Ethics Regulations95 sets the skilled standards for practice. These provisions regulate the character and extent of doctor patient confidentiality. It conjointly establishes universally recognized norms bearing on consent to a selected procedure and sets the institutionally acceptable limit for intrusive procedure or gathering to a fault personal data once it's not compulsorily needed for the same procedure. The provisions addressed underneath these laws pertain to the safety of the knowledge collected by medical practitioners and also the nature of doctor patient confidentiality.

Physicians square measure obligated to safeguard the confidentiality of patients throughout all stages of the procedure and with relevancy all aspects of the knowledge provided by the patient to the doctor, as well as data concerning their personal and domestic lives96. the sole exception to the present mandate of confidentiality is that if the law needs the revelation of sure data, or if there's a significant and acknowledgeable risk to a selected person and / or community of a inform sickness.

- **Ethical Guidelines for Biomedical Research on Human Subjects[97]**

The provisions for the regulation of privacy bearing on medicine analysis embody aspects of consent likewise as a limitation on the knowledge which will be collected and its subsequent use. The provisions of this act aim to manage the protection of privacy throughout clinical trials and through alternative strategies of analysis. The principal of consent is associate integral a part of this set of pointers. The Privacy connected data enclosed within the participant/ patient data sheet includes: the selection to forestall the employment of their biological sample, the extent to that confidentiality of records can be maintained and also the consequences of breach of confidentiality, attainable current and future uses of the biological material and of the information to be generated from the analysis and if the fabric is probably going to be used for secondary functions or would be shared with others, the chance of discovery of biologically sensitive data and publications, as well as pictures and pedigree charts.98 the rules need special
concern for privacy and confidentiality once conducting genetic family studies. ninety nine The protection of privacy and maintenance of confidentiality, specifically encompassing the identity and records, is maintained once victimisation the knowledge or genetic material provided by
for analysis functions.100 the rules need investigators to take care of confidentiality of medical specialty knowledge thanks to the actual concern that some population primarily based
data may additionally have implications on problems like national security or public safety. one zero one All documentation and communication of the Institutional ethics panel (IEC) should be dated, filed and preserved per the written procedures. knowledge of individual participants is disclosed during a court of law underneath the orders of the presiding choose, if there's a threat to a person's life, communication to the drug registration authority concerning cases of severe adverse reaction and communication to the health authority if there's risk to public health. 102

95 Code of Ethics Regulations, 2002 available at http://www.mciindia.org/RulesandRegulations/CodeofMedicalEthicsRegulations2002.aspx.

96 Code of Ethics Regulations, 2002 Chapter 2, Section 2.2.

97 Ethical Guidelines for Biomedical Research on Human Subjects. (2006) Indian Council of Medical Research New Delhi.

- **Insurance Regulatory and Development Authority (Third Party Administrators) Health Services Regulations, 2001**

The provisions of the Act that are addressed at intervals the scope of the study regulate the practices of third party directors at intervals the health care sector thus on guarantee their compliance with the fundamental principles of privacy. associate exception to the upkeep and confidentiality of knowledge confidentiality clause within the code of conduct, needs TPAs to supply relevant data to any Court of Law/Tribunal, the govt, or the Authority within the case of any investigation allotted or planned to be allotted by the Authority against the insurer, TPA or the other person or for the other reason.103 In Gregorian calendar month 2010, the IRDA notified the Insurance regulative and Development Authority (Sharing of info for Distribution of Insurance Products) Regulations104. These laws prohibit referral companies from providing details of their customers while not their previous consent.105

TPAs should maintain the confidentiality of {the data|the info|the data} collected by it within the course of its agreement associated maintain correct records of all transactions allotted by it on behalf of an insurer and are needed to refrain from mercantilism information and also the records of its business106. TPA's should keep records for a amount of not but 3 years.107

98 Informed Consent Process, Ethical Guidelines for Biomedical Research on Human Subjects (2006). Indian Council of Medical Research New Delhi. P. 21.

99 Statement of Specific Principles for Human Genetics Research, Ethical Guidelines for Biomedical Research on Human Subjects (2000). Indian Council of Medical Research New Delhi. P. 62.

100 General Ethical Issues. Ethical Guidelines for Biomedical Research on Human Subjects (2006). Indian Council of Medical Research New Delhi. P. 29.

101 Statement of Specific Principles for Epidemiological Studies, Ethical Guidelines for Biomedical Research on Human Subjects (2000). Indian Council of Medical Research New Delhi P. 56.

102 Statement of General Principles, Principle IV and Essential Information on Confidentiality for Prospective Research Participants, Ethical Guidelines for Biomedical Research on Human Subjects (2006). Indian Council of Medical Research New Delhi. P. 29.

103 The IRDA (Third Party Administrators - Health Services) Regulations 2001, (2001), Chapter 5. Section 2.

104 The IRDA (Sharing Of Database for Distribution of Insurance Products) Regulations 2010.

105 Ibid.

- **IDRA Guidelines on Outsourcing of Activities by Insurance Companies**

These pointers need the underwriter to require applicable steps that need third party service suppliers defend hint of each the underwriter and its purchasers from
intentional or unintended revelation to unauthorized persons.108

4.2 POLICY AND LAWS

- **National Policy for Persons with Disabilities, 2006[109]**

  The following provisions of the Act give for the incorporation of privacy concerns in current practices with relevancy persons with disabilities. The National Sample Survey Organization collects the subsequent data on persons with disabilities: the socio-economic and cultural context, reason behind disabilities, time of life education methodologies
  and all matters connected with disabilities, a minimum of once in 5 years.110 This knowledge is collected
  by non- medical investigators.111 there's so associate inherent limit on the knowledge collected. to boot, this data is employed just for the aim that it's been collected.
  The Special Employment Exchange, as established below The Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995 Act, collects and furnishes info in registers, concerning provisions for employment. Access to such information is proscribed to any individual World Health Organization licensed|is permitted|is allowed} by the Special Employment Exchange furthermore as persons authorized by general or special order by the govt, to access, inspect, question and duplicate any relevant record, document or info within the possession of any

establishment.112 once conducting analysis on persons with disabilities consent is needed from the individual or their relations or caregivers.113

106 Ibid.

107 List of TPAs Updated as on 19th December, 2011, Insurance Regulatory and Development Authority (2011), http://www.irda.gov.in/ADMINCMS/cms/NormalData_Layout.aspx?page=PageNo646 (last visited Dec 19, 2011).

108 The IRDA, Guideline on Outsourcing of Activities by Insurance Companies, (2011), Section 9.11. P. 8.

109 The National Policy for Persons with Disabilities, 2006, Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act, 1995, Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Rules, 1996.

110 Research, National Policy for Persons with Disabilities, 1993.

111 Survey of Disabled Persons in India. (December 2003) National Sample Survey Organization. Ministry of Statistics and Programme Implementation. Government of India.

- **HIV Interventions**

In 1992, the govt of Republic of India instituted the National AIDS management Organization (NACO) for the bar and management of AIDS. NACO aims to regulate the unfold of HIV in Republic of India through the implementation of Targeted Interventions (TIs) for many in danger populations (MARPs) primarily, sex employees, men having sex with men and folks World Health Organization
inject medication.114 The Targeted Interventions (TIs) system of testing below this organization has but raised various considerations concerning relevant policy gaps within the maintenance of the confidentiality and privacy of persons living with HIV/ AIDS. The shortcomings within the existing policy framework include: the dearth of a limitation and later confidentiality within the quantity of data collected. Project workers in TIs record the name, address and different contact info of MARPs and share this information with Technical Support Unit and
State AIDS management Societies.115 Proof of address and identity documents square measure needed to
get listed in government ART programs.116 Peer-educators operate below a system called line-listing, wont to create referrals and conduct follow-ups. Peer- educators ought to
follow-up with those that haven't gone at regular intervals for testing.117 This observe may end up in peer-educators noticing and last that the names missing square measure those that have tested positive.118 though voluntary in nature, the policy encourage the fulfillment of fulfilling of numerical targets, and in doing therefore supports unethical ways in which of testing.119
The right to privacy is a necessary demand for persons living with HIV/AIDS thanks to the potential stigmatizing and discriminatory impact of the revelation of this sensitive
information, in any type.120 the dearth of privacy rights usually fuels the unfold of the sickness and exacerbates its impact on high risk communities of people. Fears emanating from a privacy breach or a speech act of information usually deter individuals from obtaining tested and seeking medical care. The impact of such speech act of sensitive info together with the revelation of tests results to people aside from the person being tested embody low self- esteem, worry of loss of support from family/peers, loss of earnings particularly for feminine and transgender sex employees, worry of accusation for illicit sex/drug use and also the unfitness
of counselors.121 HIV positive people board constant worry of their positive standing being leaked. They conjointly withdraw from treatment as they worry individuals may see them taking their medicines and thereby guess their standing. so breaches in confidentiality and policy gaps in privacy regulation, particularly with relation to diseases like HIV conjointly prevents individuals from seeking out treatment.122

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112 Persons with Disabilities (Equal Opportunities, Protection of Rights and Full Participation) Act. 1995, Section 35.
113 Research. National Policy for Persons with Disabilities, 2003.
114 114
http://www.lawyerscollective.org/files/Anti%20rights%20practices%20in%20Targetted%20Interventions.pdf.
115 Ibid.
116 Aneka, Karnataka Sexual Minorities Forum. (2011)"Chasing Numbers, Betraying People: Relooking at HIV Services in Karnataka". P 22.
117 Supra Note 115. P. 16.
118 Ibid.
119 Supra Note 115. P. 14.
120 http://www.hivaidsonline.in/index.php/HIV-Human-Rights/legal-issues-that-arise-in-the-hiv-context.html.

4.3 PRIVACY VIOLATIONS STEM FROM POLICY AND INFORMATION GAPS:

Violations within the care sector that stem from policy formulation furthermore and implementation gaps123 embody the speech act of non-public health info to 3rd parties while not consent, inadequate notification to a tolerant a knowledge breach, unlimited or extra assortment of non-public health information, assortment of non-public health information that's not correct or relevant, the aim of aggregation information isn't mere, refusal to produce medical records upon request by consumer, provision of non-public health information to public health, research, and business uses while not de-identification of information and improper security standards, storage and disposal. The speech act of non-public health info has the potential to be embarrassing, stigmatizing or discriminatory.124 what is more, numerous product like employment, life, and medical insurance, may be placed at risk125 if the flow of medical info weren't restricted.126

Disclosure of non-public health info is allowable and doesn't quantity to a violation of privacy within the following situations: 1) throughout referral, 2) once demanded by the court or by the police on a written requisition, 3) once demanded by insurance corporations as provided by the Insurance Act once the patient has relinquished his rights on taking the insurance, and 4) when needed for specific provisions of compensation cases, consumer protection cases, or for revenue enhancement authorities,127 5) sickness registration, 6) disease investigations, 7) vaccination studies, or 8) drug adverse event reportage.128

121 Chakrapani et al, (2008) 'HIV Testing Barriers and Facilitators among Populations at-risk in Chennai, India', INP, p. 12.
122 Supra Note 115. P. 24.
123 Nissenbaum, H. (2004). Privacy as Contextual Integrity. Washington Law Review, 79(1), 101-139.
124 Ibid.
125 Thomas, J. (2009). Medical Records and Issues in Negligence, Indian Journal of Urology : IJU : Journal of the Urological Society of India, 25(3), 384-388. doi:10.4103/0970-1591.56208.
126 Ibid.
127 Plaza, J., & Fischbach, R. (n.d.). Current Issues in Research Ethics : Privacy and Confidentiality. Retrieved December 5, 2011, from http://ccnmtl.columbia.edu/projects/cire/pac/foundation/index.html.
128 Ibid.

CHAPTER-IV

JUDICIAL RESPONSE

"When a doctor does go wrong he is the first of criminals. He has nerve and he has knowledge." - Arthur Conan Doyle

CHAPTER-IV

JUDICIAL RESPONSE

4.1 THE SUPREME COURT ON CONSENT

In **Samira Kohli v. Dr. Prabha Manchanda**,[129] the Supreme Court of Republic of India states that consent within the context of a doctor–patient relationship is outlined as grant of permission by the patient for associate act to be meted out by the doctor, like a diagnostic, surgical or therapeutic procedure. Consent are often implicit in some circumstances from the action of the patient. This order provides the principles of consent with relation to medical treatment and therapeutic investigations and not for medical research/clinical trials as follows:

1. A doctor should request and secure the consent of the patient before commencing a 'treatment'. The consent therefore obtained ought to be real and valid; the consent ought to be voluntary; and therefore the consent ought to air the idea of adequate info regarding the character of the treatment procedure, so she/he is aware of what she/he is willing to.
2. A balance ought to be maintained between the necessity for revealing necessary associated adequate info and at identical time avoid the likelihood of the patient being deterred from agreeing to a necessary treatment or giving to endure an excess treatment.
3. Consent given just for a procedure can not be thought-about as consent for treatment. Consent given for a particular treatment procedure isn't valid for a few different treatment or procedure.
4. There are often a typical consent for diagnostic and operative procedures wherever they're contemplated. There may also be a typical consent for a selected operation and any|an extra} or further procedure that will become necessary throughout the course of surgery.
5. the character and extent of data to be stocked with by the doctor to the patient to secure the consent needn't be of the rigorous and high degree mentioned in Canterbury130 however ought to be of the extent that is accepted as traditional and correct by a body of medical men consummate and experienced therein specific field. it'll depend on the physical and mental condition of the patient, the character of treatment, and therefore the risk and consequences connected to

the treatment. However, there's a major distinction within the nature of specific consent of the patient, referred to as 'real consent' within the Great Britain and as 'informed consent' within the USA. In the UK, the weather of consent ar outlined with respect to the patient and a consent is taken into account to be valid and 'real' once (i) the patient provides it voluntarily with none coercion;

(ii) the patient has the capability and competency to relinquish consent; and (iii) the patient contains a minimum level of data regarding the character of the procedure to that she/he is willing to. On the opposite hand, the thought of 'informed consent' developed by yank courts, whereas retentive the essential necessities of consent, shifts the stress to the doctor to disclose necessary info to the patient to secure his/her consent.131

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129 (2008) 2SCC 1 Para 32.

130 Canterbury v Spence 464 F.2d 772 (D.C. Cir. 1972).

The Supreme Court of Republic of India states that the 'real consent' thought evolved in Bolam132 and Sidaway133 are most well-liked to the 'reasonably prudent patient test' in Canterbury,134 visible of the bottom realities in medical and aid state of affairs in Republic of India. If medical practitioners and personal hospitals become a lot of and a lot of commercialised, and if there's a corresponding increase within the awareness of patient's rights among the general public, inevitably, a day could return once it should be shifted towards Canterbury.135

The duty of confidence is well established in the common law. In **AG v. Guardian** Newspapers136 (the Spycatcher case), the court explained that the duty of confidence arises from associate obligation in smart conscience. Lord Goff explicit that a obligation of confidence arises: once counselling involves the information of an individual (the confidant) in circumstances wherever he has notice, or is command to possess united, that the knowledge is confidential, with the impact that it might be simply all told the circumstances that he ought to be precluded from revealing the knowledge to others.

Medical info is usually treated as counselling. at intervals the context of medical law confidentiality is additionally protected by Article 8(1) of the Convention whereby everybody contains a right to respect for his personal life, which can embrace medical matters. However, the duty to respect confidentiality isn't absolute and, as per Lord Goff are often trumped within the event of a weightier public interest within the revelation. Likewise, the derogation below Article 8(2) of the Convention serves to qualify the Article 8(1) right if interference
with the proper is in a veryccordance with the law and necessary in a democratic society. Thus, establishing that revelation is excusable would stop a claim supported breach of confidentiality. From an individual's rights perspective, justification below Article 8(2) was apparent in **Z v. Finland**137

131 (2008) 2SCC 1 Para 14.
132 Bolam v Friern Hospital Management Committee (1957) 2 All ER 118.
133 Sidaway v Bethlem Royal Hospital Governors & Ors. (1985) 1 All ER 643.
134 Supra Note 129.
135 (2008) 2SCC 1 Para 33.
136 (2) [1990] 1 AC 109.

Z was married to an HIV positive man who had boon danced with a number of sexual offences. The police sought and gained access to Z's medical records to determine when her husband had become aware of his HIV status. The European Court of Human Rights held that seizure of Z's medical records did not violate Article 8 because of the legitimate aim being pursued and the proportionate measures that were being used. The court accepted that the interests of patients and the community in protecting confidentiality of medical data could be outweighed by public interests in the investigation and prosecution of crime. This principle was again tested in **Szuluk v. United Kingdom**[138]. The applicant had been sentenced to 14 years' imprisonment for conspiring to supply Class A drugs. On return to prison following cranial surgery he required continued monitoring and biannual hospital check-ups. He subsequently applied for judicial review of the prison authority's decision to refuse to allow him to correspond with his consultant in confidence, on the grounds of interference with his rights to privacy as protected by Article 8(1) of the Convention. The European Court of Human Rights considered that in the circumstances the applicant's Article 8 rights had been violated. It was considered significant that he had been suffering from a life-threatening disorder that required continuous medical supervision. In the circumstances monitoring his medical correspondence had not struck a fair balance with his right to privacy.

Stone v. South East Coast SHA[139] concerned the issue of confidentiality with respect to medical treatment. Michael Stone was a convicted murderer who sought to suppress publicationof the homicide enquiry which included reference to his medical treatment. The judge concluded that a redacted version of the report would not be appropriate and might also be perceived to be a 'cover up'. The judge accepted that the most persuasive argument in favour of Mr Stone was his entitlement to the right of privacy as protected by Article 8 of the Convention.The force of that claim was, however, outweighed by other considerations such as the genuine public interest in knowing of the actual care and treatment that had been given in order to reach an informed assessment of the case. On undertaking a balancing exercise

137 (1997) 25 EHRR 371.
138 (2009) 108 BMLR 190.
139 [2006] EWHC 1608.

Z was married to associate HIV positive man United Nations agency had boon danced with variety of sexual offences. The police sought-after and gained access to Z's medical records to see once her husband had become attentive to his HIV standing. the eu Court of Human Rights command that seizure of Z's medical records didn't violate Article eight thanks to the legitimate aim being pursued and therefore the proportionate measures that were being employed. The court accepted that the interests of patients and therefore the community in protective confidentiality of medical information might be outweighed by public interests within the investigation and prosecution of crime. This principle was again tested in Szuluk v. United Kingdom138. The someone had been sentenced to fourteen years' imprisonment for conspiring to produce category a medication. On come to jail following bone surgery he needed continuing watching and time period hospital check-upsHe afterward applied for review of the jail authority's call to refuse to permit him to correspond along with his authority in confidence, on the grounds of interference along with his rights to privacy as protected by Article 8(1) of the Convention. the eu Court of Human Rights thought-about that within the circumstances the applicant's Article eight rights had been desecrated. . it absolutely was thought-about vital that he had been affected by a serious disorder that needed continuous medical superintendence. within the circumstances watching his medical correspondence had not smitten a good balance along with his right to privacy.

Stone v. South geographical region SHA139 involved the problem of confidentiality with regard to medical treatment. archangel Stone was a condemned slayer WHO sought-after to suppress publication of the killing enquiry including regard to his medical treatment. The choose all over that a redacted version of the report wouldn't be acceptable and may also be gave the impression to be a 'cover up'. The choose accepted that the foremost persuasive argument in favour of man Stone was his title to the proper of privacy as protected by Article eight of the Convention. The force of that claim was, however, outweighed by alternative issues like the real public interest in knowing of the particular care associated treatment that had been given so as to succeed in an hip assessment of the case. On endeavor a reconciliation exercise between his right to confidentiality and also the public interest, revelation of the medical data was even.

It is potential that Articles six (the right to a good trial) and ten (freedom of expression) may also have interaction within the context of the Article eight right to privacy. In Joseph Campbell v. MGM Ltd140, mannequin Naomi Joseph Campbell accepted that the media was entitled to disclose that she was a
drug addict. However, she sought-after to stop publication of her group action at Narcotics Anonymous aboard photographic proof on the grounds that this amounted to a breach of her privacy. The newspaper sought-after to publish this data below the liberty of expression provision of Article ten of the Convention. In reconciliation the rights of Article ten against Article eight, peeress Hale declared that during this explicit instance, publication would cause Ms Joseph Campbell hurt which it absolutely was the chance of hurt that mattered at that stage, instead of proof that actual hurt had occurred. Those making an attempt to live through addiction required dedication and commitment, together with positive reinforcement from others. Organisations like Narcotics Anonymous might do a lot of sensible and media interference at s stage once the patient was acknowledged to be 'fragile' might cause a substantial occurrence. In R (on the applying of B) v. Stafford Combined Court141, B was a 14-year-old woman WHO was the most witness within the trial of the litigant, WHO was defendant (and afterwards convicted) of sexually abusing her. The defendant's advisers sought-after to access B's medical specialty records on the grounds that these were relevant to her quality as a Witness. In reconciliation B's right to confidentiality below Article eight and also the defendant's right to a good trial below Article six, the choose all over (at

1st instance) that the proper to a good trial outweighed the proper to confidentiality and ordered revelation of the girl's records. This call was trenchantly criticised on charm on the grounds that it absolutely was unacceptable for a 14-year-old girl with a history of tried suicide to be delivered to court at short notice with the apparent alternative of agreeing to revelation of her medical specialty records or to delay a shot that was already inflicting her distress. B had not been given due notice of the applying for the witness summons, nor had she been given the chance to form representations before the order was created. The Court of charm all over that interference together with her rights (of confidentiality) wasn't necessary at intervals the derogation of Article 8(2) and if truth be told that the court had acted in a very approach that was incompatible with B's Convention rights.

140 [2004] UKHL 22.

141 [2006] EWHC 1645 (Admin).

Breach of Confidence of Patients

Mr. X v. Hospital Z[142]

In Bharat the foremost vital case is X vs. Hospital Z because it showcases associate exception to action against breach of confidentiality. during this case the litigant was progressing to marry an exact Ms. Y however the wedding was referred to as off on the grounds of a biopsy conducted at an exact hospital Y that reputed that the litigant was HIV +ve. The litigant then approached the National client Disputes Redressal Commission for damages against the defendants, on the bottom that the knowledge that was needed to be unbroken secret below medical ethics was disclosed illicitly and, therefore, the defendants were prone to pay damages. The counsel for the litigant had contended that the principle of 'duty of care', as applicable to persons within the medical community, includes the duty to take care of confidentiality and since this duty was profaned by the respondents, they're liable in damages to the appellant.

A Code of Medical Ethics has been created by the Indian Medical Council that, provides as below 'Do not disclose the secrets of a patient that are learnt within the exercise of your profession. Those is also disclosed solely in a very court of law below orders of the Presiding choose.' The plaintiff's counsel so argued that the defendants were below a obligation to take care of confidentiality on account of the code of medical ethics. but the court command that the projected wedding carried with it the health risk to associate recognizable one that had to be protected against being infected with the disease from that the litigant suffered.

The court additionally uses what the final Medical Council of england says concerning HIV infection, "When diagnosing has been created by a specialist and also the patient when acceptable content, still refuses permission for the final professional person to learn of the result, that request for privacy ought to be revered. the sole exception would be once failure to disclose would place the health of the health-care team at serious risk. All individuals receiving such data should think about themselves to be below a similar obligations of confidentiality because the doctor primarily answerable for the patient's care. sometimes the doctor might need to disclose a diagnosing to a 3rd party aside from a health-care skilled.

The Council suppose that the sole grounds for this ar once there's a heavy and identifiable risk to a particular person,
who, if not therefore informed would be exposed to infection... A doctor might contemplate it a obligation to confirm that any sexual partner is informed despite the patient's own needs."
This AN expressly clear guideline serving to the court build a call within the defendant's favour.

The right to confidentiality, if any, unconditional within the litigant wasn't enforceable therein scenario. because the right to confidentiality in India is due to the correct to privacy beneath Article twenty one and also the cases of Kharak Singh v. State of U.P143 and Govind v. State of M.P.144 the court command that like all alternative rights this right isn't absolute and subject to affordable restrictions.
The court command that if the wedding had proceeded in due course, then Ms. Y would sure are infected with the deadly unwellness AIDS and so her 'right to life' that's, the correct to steer a healthy life would be profaned. so within the interest of public morality the court set that the charm of the litigant is while not advantage.
Doctor patient confidentiality is command to be one amongst the inviolable rights in keeping with

the oath and it's statute in India within the sort of the Code of Medical Ethics by the Indian Medical Council beneath the Indian Medical Council Act, 1956. This bases itself on the International Code of Medical Ethics. That right is that a doctor cannot reveal details of the patients being treated by him even once his death except in a very court of law. in keeping with the researchers this right is extraordinarily vital because it provides legal remedy to individuals
wronged by medical practitioners WHO have profaned such a very important right.145

Here we tend to perceive that within the interests of the general public override that of the precise person whose confidentiality was broken. In our read this can be fascinating as 'blind enforcement' of rights while not taking into thought public welfare doesn't facilitate anybody. therefore the courts' position is that this right is vital and excusable except in numerous things like in cases of public morality.

142 1988 8 SCC 296.

4.1.1 Privacy Regulations in Healthcare Sector-

The following cases are wont to deliberate upon details of rivalry at intervals the compass of the implementation and impact of Privacy laws gain the tending sector.

This includes the character and extent of privacy enjoyed by the patient and instances wherever within the privacy of the patient may be compromised in light-weight of public interest issues.

Mr. Surupsingh Hrya Naik v. State of Maharashtra, (2007)

Since the Code of Ethics laws ar solely delegated legislation, it had been command within the case

of Mr. Surupsingh Hrya Naik v. State of Maharashtra146, that these wouldn't prevail over the correct to info Act, 2005 (RTI Act) unless the data sought-after falls beneath the exceptions contained in Section eight of the RTI Act. This case addressed the vital purpose of rivalry of whether or not creating the health records public beneath the RTI Act would represent a violation of the correct to privacy. These health records were needed to see why the convict in question was allowed to remain in a very hospital as against jail. during this context the urban center tribunal command that the correct to info Act supersedes the regulation that mandate the confidentiality of an individual, or during this case a convict's medical records. it had been command that the medical records of an individual sentenced or condemned or remanded to police or judicial custody, if throughout that amount such person is admitted in hospital and institution, ought to be created offered to the person asking the data provided such hospital institution is maintained by the State or Public Authority or the other Public Body. it's solely in rare and in exceptional cases and permanently and valid reasons recorded in writing will the data could also be denied. the choice during this case command that The RTI Act 2005 would come after The Medical Council Code of Ethics. The health records of a personal in judicial custody ought to be created offered beneath the Act and may solely be denied in exceptional cases, for valid reasons.

Radiological & Imaging Association v. Union of India,147 (2011)

On fourteen Gregorian calendar month 2011 a circular was issued by the Collector and District adjudicator, Kolhapur requiring the Radiologists ANd Sonologists to submit an on-line kind "F" beneath the PNDT Rules. This was challenged by the tomography and Imaging Association, inter alia, on the bottom that it violates the privacy of their patients. Deciding the higher than issue the urban center tribunal command that. the pictures keep within the silent observer don't seem to be transmitted on-line to any server and so stay embedded within the ultra-sound machine. Further, the silent observer is to be opened solely for the asking of the Collector/ the civil MD within the presence of the involved radiologist/sonologist/doctor guilty of the Ultra-sound Clinic. In light-weight of those considerations and also the undeniable fact that the `F' kind submitted on-line is submitted solely to the Collector and District adjudicator is not any violation of the doctor's duty of confidentiality or the patient's right to privacy. it had been any ascertained that, the contours of the correct to privacy should be circumscribed by the compelling public interest flowing through every and each provision of the laptop & PNDT Act, once browse within the background of the subsequent figures of declining sex magnitude relation within the last 5 decades. the utilization of

a Silent Observer system on a instrument has requisite safeguards and doesn’t violate privacy rights. The declining sex magnitude relation of the country was thought-about a compelling public Interest that might come after the correct to privacy.

Smt. Selvi and Ors. v. State of Karnataka148 (2010)

The Supreme Court command that involuntary subjection of someone to narco analysis, medical instrument take a look at and brain-mapping violates the 'right against self-incrimination' that finds
its place in Article 20(3)149 of the Constitution.59 The court additionally found that narco analysis desecrated individuals' right to privacy by intrusive into a "subject's mental privacy," denying a chance to settle on whether or not to talk or stay silent, and physically restraining a theme to the situation of the tests and amounted to cruel, inhuman or degrading
treatment.150 The Supreme Court found that Narco-analysis desecrated associate degree individuals' right to privacy by intrusive into a "subject's mental privacy," denying a chance to settle on whether or not to talk or stay silent.

143 1964 SCR (1) 332.

144 1975 SCR (3) 946.

145 Nitin Kumar, Confidentiality- An emerging tort in India (Dec. 1 ,2019, 10:52 p.m.) http://www.legalservicesindia.com/article/1541/Confidentiality,-An-Emerging-Tort-In-India.html.

146 AIR 2007 Bom 121.

147 AIR 2011 Bom 171.

Neera Mathur v. Life Insurance Corporation (LIC),[151] (1991)

In this case the complainant oppose a wrongful termination once she availed of maternity leave. LIC needed girls candidates to furnish personal details like their discharge cycles, conceptions, pregnancies, etc. at the time of appointment. Such a demand was command to travel against the modesty and dignity of girls. The Court command that termination was solely attributable to disclosures in application, that was command to be intrusive, embarrassing and mortifying. LIC was directed to delete such queries.

The Court failed to visit the term privacy but it used the term personal details likewise as modesty and dignity, however failed to specifically link them to the proper to life or the other

fundamental right. These terms (modesty associate degreed self-respect) area unit sometimes not connected to privacy however though they will be the hurt that comes from an intrusion of one's privacy. The Supreme Court command that queries associated with associate degree individual's fruitful problems area unit personal details and will not be asked within the service application forms.

148 (2010) 7 SCC 263.

149 No person accused of any offence shall be compelled to be a witness against himself', (the 'right to silence').

150 http://www.hrdc.net/sahrdc/hrfeatures/HRF205.pdf.

151 AIR 1992 SC 392.

Ms. X vs. Mr. Z & Anr,152 (2001)

In this case, the metropolis state supreme court command that associate degree aborted fetus wasn't an area of the body of a girl and allowed the desoxyribonucleic acid take a look at of the aborted fetus at the instance of the husband. the applying for a desoxyribonucleic acid take a look at of the fetus was oppose by the married woman on the bottom of "Right to Privacy".7In this regard the court command that The Supreme Court had antecedently determined that a celebration is also directed to produce blood as a desoxyribonucleic acid sample however can not be compelled to try to to thus. The Court could solely draw associate degree adverse interference against such party World Health Organization refuses to follow the direction of the Court during this respect. The position of the court during this case was that the claim that the preservation of a fetus within the laboratory of the All Asian nation Institute of life science, violates the petitioner's right to privacy, can not be amused because the fetus had been voluntarily discharges from her body antecedently, together with her consent. The foetus, that she herself has discharged is claimed to be subjected to desoxyribonucleic acid take a look at. Thus, in light-weight of the actual facts and also the context of the case, it had been command that petitioner doesn't have any right of privacy.

It is necessary to notice here that the actual fact that the Court is relying upon the principles arranged down within the case of R. Rajagopal appears to counsel that the Court is treating organic tissue preserved in a very public hospital within the same manner because it would treat a public document, to that degree because the exception to the proper to privacy cares. A woman's right to privacy doesn't touch a fetus, that isn't any longer an area of her body. the proper to privacy could arise from a contract likewise as a particular relationship, together with a nuptial. The principle during this case has been arranged down in broad enough terms that it's going to be applied to alternative body components that are disassociated from the body of the individual.

B.K. Parthasarthi v. Government of state,153 (1999)

In this case, the state state supreme court was to come to a decision the validity of a provision within the state panchayet rule Act, 1994 that stipulated that somebody having over 2 kids ought to be disqualified from contesting elections. This clause was challenged on variety of grounds together with the bottom that it desecrated the proper to privacy. The Court, in

deciding upon the proper to privacy and also the right to fruitful autonomy, held that, ‘‘The impugned provision, i.e. Section 19(3) of the aforementioned Act doesn't compel directly anyone to prevent reproduction, however solely disqualifies somebody World Health Organization is otherwise eligible to hunt election to varied public offices returning inside the reach of the state panchayet rule Act, 1994 or declares such persons World Health Organization have already been holding such offices to be disqualified from continued in such offices if they multiply over 2 kids. Therefore, the submission created on behalf of the petitioners 'right to privacy' is infringed, is unreasonable and should be rejected.’’

M. Vijaya v. Chairman and Managing Director, Singareni Collieries Co. Ltd.[154] (2001)

The petitioner alleged that she had contractile the HIV virus thanks to the negligence of the authorities of Maternity and Family Welfare Hospital, Godavarikhani, a hospital below the management of Singareni Collieries Company Ltd., (SCCL), in conducting relevant preventative blood tests before transfusion of blood of her brother (donor) into her body once she was operated for extirpation (Chronic Cervicitis) at the hospital. The petition was at first filed as a Public Interest judicial proceeding, that the court punctually distended so as to handle the matter of the dearth of adequate preventative measures in hospitals, thereby additionally coping with problems with medical confidentiality and privacy of HIV patients. The court therefore deliberated upon the conflict between the proper to privacy of associate degree HIV infected person and also the duty of the state to stop more transmission and held:
In the interests of the overall public, it's necessary for the State to spot HIV positive cases and any action taken therein regard can not be termed as unconstitutional.

As underneath Article forty seven of the Constitution, the State was underneath associate degree obligation to require all steps for the advance of the general public health. A law designed to realize this object, if honest and cheap, in our opinion, won't be in breach of Article twenty one of the Constitution of Republic of India.

However, associate degreeother side of the matter is whether or not compelling an individual to require HIV take a look at amounts to denying the proper to privacy? The Court analyzed the prevailing domestic legislation to gain the conclusion that there's no general law which will compel an individual to bear an HIV-AIDS test.

However, specific provisions underneath the jail Laws155 give that as presently as a unfortunate is admitted to jail, he's needed to be examined medically and also the record of prisoner's health is to be maintained during a register. Further, underneath the ITP Act, the sex employees also can be compelled to bear HIV/ AIDS take a look at.156 to boot, underneath Sections 269 and 270 of the Indian legal code, 1860, an individual is punished for negligent act of spreading infectious diseases.

After mapping legislation that let the invasion of bodily privacy, the Court over that they're not comprehensive enough to alter the State to gather data concerning patients of HIV/AIDS and devise applicable methods and so the State ought to draft a replacement legislation during this regard. any the Court gave bound directions to the state concerning a way to handle the epidemic of HIV/AIDS and one amongst those directions was that the "Identity of patients World Health Organization return for treatment of HIV+/AIDS mustn't be disclosed in order that different patients will step up for taking treatment."

The right of generative autonomy may be a part of the proper to privacy. A provision disabling an individual from standing for elections thanks to the amount of youngsters had, doesn't violate the proper to privacy because the object of the legislation isn't to violate the autonomy of a private however to mitigate the increment within the country. Measures to manage increment shall be

thought of legal unless they impermissibly violate a elementary right.
The right to privacy of an individual suspected to be HIV+ would be subordinate to the facility and duty of the state to spot HIV+ patients so as to shield public interest and improve public health. but any law designed to realize this object should be honest and cheap. during a conflict between the individual's privacy right and also the public's right in handling the cases of HIV-AIDS, the legal code principle 'Salus Populiest Suprema' (regard for the general public wealth is that the highest law) applies once there's a necessity.

154 AIR 2001 AP 502.

155 See Sections 24, 37, 38 and 39 of The Prisons Act, 1894 (Central Act 9 of 1894) Rules 583 to 653 (Chapter XXXV) and Rules 1007 to 1014 (Chapter LVII) of Andhra Pradesh Prisons Rules, 1979.

Sharda v. Dharmpal,[157] (2003)

The basic question during this case was whether or not a celebration to a divorce continuing is compelled to a medical exam. The better half within the divorce continuing refused to submit herself to medical exam to work out whether or not she was of unsound mind on the bottom that such associate degree act would violate her right to non-public liberty. Discussing the balance between protective the right to privacy and different principles which will be concerned in marital cases like the 'best interest of the kid' just in case child custody is additionally in issue, the Court held:

"Privacy" is outlined as "the state of being free from intrusion or disturbance in one's personal life or affairs". However, the proper to privacy in Republic of India, is just given through an intensive interpretation of Article twenty one and can't thus in associate degreey circumstance be thought of an absolute right. psychological state treatment involves revealing of one's most personal feelings but, like all different privilege the psychotherapist-patient privilege isn't absolute and should solely be recognized if the profit to society outweighs the prices of keeping the data personal. so if a child's best interest is jeopardized by maintaining confidentiality the privilege could also be restricted." Thus, the facility of a court to direct medical exam of a celebration to a marital proceeding during a case of this nature cannot beheld to violate the petitioner's right to privacy. If the simplest interest of a baby is in issue within the case then the patient's right to privacy and confidentiality would get restricted. the proper to privacy of a private would be subordinate to the facility of a court to gain a conclusion during a marital dispute and also the right of a celebration to shield his/her rights during a Court of law would trump the proper to privacy of the opposite.

156 Section 10-A,17(4) ,19(2) Immoral Traffic (Prevention) Act 1956.

157 AIR 2003 SC 3450.

CHAPTER-V

INTERNATIONAL BEST PRACTICE AND RECOMMENDATIONS

“Developments in medical technology have long been confined to procedural or pharmaceutical advances, while neglecting a most basic and essential component of medicine: patient information management.” - John Doolittle

CHAPTER-V

INTERNATIONAL BEST PRACTISE AND RECOMMENDATIONS

5.1 THE EU DATA PROTECTION DIRECTIVE-

Data protection laws normally ask for to manage ‘personal data’ regarding people or ‘data subjects’, handled by each ‘data processors’ and ‘data controllers’.158 Notably, not all info a few person will trigger the applying of information protection law, since only information that affects associate individual’s privacy are often thought of ‘personal’.159 The controller (or the methodor selected by the controller to process the data) is accountable for the way during which a subject’s personal knowledge is processed.160

The EU knowledge Protection Directive acts because the basis for varied national knowledge protection laws in EU Member States, providing eight knowledge protection principles to the States that apply the Directive.161 The core knowledge protection principle is that the truthful and lawful process of private info.162 the knowledge should be obtained for one or additional mere and lawful functions, and should be relevant to the aim that they're processed.163 the information should not be hold on for extended than is critical for the required purpose.164 any, each the controller associated processor area unit beneath an obligation to enforce applicable technical and organizational measures to safeguard against unlawful process.165 The processor is subject to a similar rigorous conditions obligatory on the controller, World Health Organization remains beneath an additional obligation to observe the processor’s compliance with the protection measures for the length of the agency.166

The Directive additionally lays down a general presumption against the adequacy of information protection laws in third countries.167 wherever transfer of information takes place between States that have enforced the Directive by implementing similar domestic laws, the information controller (who is in possession of the information) are often assured that the amount of protection offered within the recipient country matches that within the host State.168 wherever transfer of information takes place between a Member State and a 3rd country, however, the adequacy of protection offered by the third country are evaluated in light-weight of close circumstances, like nature
of data and purpose and length of the projected process operation.169
The European Court of Human Rights ('ECHR') stressed the importance of protective a person's health knowledge in I v. Suomi in 2008.170 The case concerned associate worker of a watch clinic, erstwhile a patient at the clinic, whose HIV standing became known to her colleagues thanks to free access to the patient register containing info on diagnoses and treatment.171 The ECHR noted within the case that the "sensitive problems close this disease" would build the need of confidentiality significantly vital within the
applicant's case.172 This observation of the ECHR places associate obligation on knowledge controllers to stay all confidential knowledge safe from unauthorized access.173

An official EU knowledge protection regulation174 was issued in Gregorian calendar month 2012. A key objective of this was to introduce an identical policy directive across all member states. The regulation, once enforced was to be applicable all told member states and left no space for alteration or amendments.

The regulation incorporate Privacy Impact Assessments175 once there area unit specific risks to privacy which might embody identification, sensitive knowledge associated with health, genetic material or biometric info. this is often a crucial step towards evaluating the character and extent of privacy regulation needed for varied procedures and would be effective within the creation of a scientific structure for the implementation of those laws. The regulation additionally established the necessity for express consent for sensitive personal knowledge. the premise for this is often associate inherent imbalance within the positions of {the knowledge|the info|the information} subject and therefore the data controller, or in less complicated terms the patient and therefore the hospital or the life sciences company conducting the analysis.
Thus, understood consent isn't enough176 and a necessity arises to proceed with the testing only there's express consent.

158 UK Data Protection Act, 1998 (c. 29), S.1(1) (This implementing legislation ensures compliance with the data protection principles enunciated in the Data Protection Directive).
159 Durant v. Financial Services Authority, 2003 EWCA Civ 1746 (This case defines data as 'personal' only if it 'affects his privacy'. According to Durant, information should be (i) 'biographical in a significant sense' and (ii) second, the focus should be on the data subject, excluding information held by the data controller that contains a passing reference to particular individuals).
160 UK Data Protection Act, 1998, S.1(1) (This provision "data controller" means, subject to sub- section (4), a person who (either alone or jointly or in common with other persons) determines the purposes for which and the manner in which any personal data are, or are to be processed).
161 Data Protection Directive (These principles were part of the Council of Europe's attempts to harmonise national laws on data protection in its 1973 and 1974 resolutions, and are laid down in Schedule I of the Data Protection Act, 1998).

Embedded among the regulation is that the right to be forgotten177 whereby patients will request for his or her knowledge to be deleted once they need been discharged or the trial has been all over. within the Indian state of affairs, patient info is unbroken for extended periods of your time. this will be subject to unauthorized access and misuse. The deletion of patient info once it's been used for the aim that it absolutely was collected is therefore imperative towards the creation of associate surroundings of privacy protection.
Article eighty one of the regulation specifies that health knowledge could also be processed just for 3 major processes178

a) In cases of Preventative or activity drugs, diagnosis, the care, treatment or management of care services, and in cases wherever the information is processed by the care professionals, the information is subject to the requirement of skilled secrecy;

b) Considerations of public interest bearing an on the spot nexus to public health, for instance, the protection of legitimate cross border threats to health or guaranteeing a high commonplace of quality and safety for healthful merchandise or services;

c) Or alternative reasons of public interest like social protection.

An added concern is that the nature and extent of consent. The consent obtained throughout a trial might not continually be comfortable to hide further analysis even in instances of information being coded adequately. Thus, it's going to not be potential to anticipate further analysis while concluding initial analysis. Article 83179 of the regulation prohibits the utilization of information collected for an extra purpose, alternative that the aim that it absolutely was collected

Lastly, the regulation covers knowledge which will be transferred outside the EEA, unless there's an extra level of information protection. If a court settled outside the EU makes a call for participation for the speech act of private knowledge, previous authorization should be obtained from the native knowledge protection authority before such transfer is formed. it's imperative that this be enforced among Indian legislation as presently there's no mechanism to manage the cross border transfer of private knowledge.

158 UK Data Protection Act, 1998, Schedule 2 and 3 (Conditions for fair and lawful processing of personal datainclude (i) obtaining the patient's consent and (ii) that data must be processed in the patient's 'vital interests').

159 UK Data Protection Act, 1998, Schedule 1, Part 1, Principles 2 and 3.

160 UK Data Protection Act, 1998, Schedule 1, Part, Principle 5.

161 UK Data Protection Act, 1998, Schedule 1, Part I, Principle 7 (Appropriate technical and organizational measures shall be taken against unauthorized or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data).

162 P. Room & F. F. WATERHOUSE, BUTTERWORTHS DATA SECURITY LAW AND PRACTICE 68 (2009).

163 Data Protection Directive, Arts. 25 and 26.

164 Health Systems Governance in Europe: The Role of EU Law and Policy 564 (E. Mossialos, G. Permanand, R. Baeten & T. K. Hervey eds., 2010) ('Health Systems Governance in Europe').

165 Ibid.

166 See I v. Finland, Application No. 20511/03: 2008 ECHR 623 (The ECHR stated (upholding the Court's previous decision in Z v. Finland, (1988) 25 EHRR 371) that the protection of personal data, in particular medical data, is of fundamental importance to a person's enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the European Convention on Human Rights. Respecting the confidentiality of health data is a vital principle in the legal systems of all the Contracting Parties to the Convention).

167 Room & Waterhouse, supra note 157.

168 Ibid.

169 See Supra Note 161.

170 http://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf. Article 33, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.

171 Article 4 (Definition of "Data Subject's Consent"), Article 7, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) <http://ec.europa.eu/justice/data- protection/document/review2012/com_2012_11_en.pdf> [Accessed on 14th May, 2014].

172 Article 17, "Safeguarding Privacy in a Connected World – A European Data Protection Framework for the 21st Century" COM(2012) 9 final. Based on, Article 12(b), EU Directive 95/46/EC – The Data Protection Directive at <http://www.dataprotection.ie/docs/EU-Directive-95-46-EC-Chapter-2/93.htm> [Accessed on 14th May, 2014].

173 Article 81, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) <mhttp://ec.europa.eu/justice/data-protection/document/review2012/com_2012_11_en.pdf> [Accessed on 14th May, 2014].

5.2 COMMON LAW POSITION UNDER THE UK DATA PROTECTION ACT, 1998-

Ordinarily, associate degreeonymized data mustn't gift a lot of of an moral quandary to health care professionals. The mere de-personalisation of patient information, however, doesn't provide ample justification for decreasing the extent of protection usually afforded to personal information.180 Personal information is outlined underneath S.1(1) of the DPA as ‘‘data that relate to a living individual United Nations agency are often identified- (a) from the information, or (b) from those information and different data that is within the possession of, or is probably going to come back into the possession of the information controller.’’The European Economic Community information Protection Directive states that ‘‘the principles of protection shall not apply to information rendered anonymous in such the simplest way that the information subject is not any longer identifiable.’’181 so, it's evident that the take a look at for de-personalisation of knowledge should involve over mere anonymisation of the information.

174 Article 83, Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.

175 Beyleveld, D. & Histed, E., Case Commentary: Anonymisation is Not Exoneration, (1999) 4 med. L.i. 69 73-74 cited in pRinCipLeS oF mediCAL LAW 658 (A. Grubb, J. Laing & J. McHale eds., 2010) (‘PRINCIPLES OF MEDICAL LAW’) (For example, a woman who is a devout Catholic may be opposed to the use of her data in research for chemical contraceptive methods).

The question of whether or not the utilization of anonymized patient information could be a breach of patient privacy was examined by the Court of attractiveness in R v. Department of Health, ex p supply
Informatics.182 a knowledge assortment company, during this case, needed to sell anonymised information collected from pharmacists to as- bound the prescribing habits of general physicians. The Court of attractiveness control that no duty of confidence arises in relevancy totally anonymised data. This line of reasoning fallaciously assumes that a patient's fairly expectation of privacy is restricted to primary uses of diagnosable data.183 Primary uses might conceivably embrace the change of a hospital's record of a patient's case history or the pursuit of specific analysis objectives, that the previous consent of the information subject has been obtained. The read taken in supply scientific discipline seems to be out of line with the expansive interpretation of associate degree individual's non-public life in a very recent call of the ECHR.184 The ECHR under- stood the conception of 'private life' broadly speaking to incorporate a person's name, family life and data a few person's health, thereby protective a person's right to manage all aspects of his life.185
S.11 of the UK's information Protection Act, 1998 ('DPA') entitles a personal to give notice {the information|the info|the information} controller to stop process 'for the needs of direct marketing' any personal data of that he's the information subject. though the argument wasn't thought of in supply scientific discipline, information subjects, whose data was being anonymised then commercially exploited by the information assortment company, ought to are notified on the purposes of anonymisation.186 additional, since S.1(1) of the DPA defines 'processing' as 'adaptation or alteration', patients whose information is being anonymised ar entitled to notification by the information controllers concerning the needs of such 'processing' underneath the second
data protection principle.187

176 Data Protection Directive, Recital 26.
177 (1995) 4 All ER 185, rev'd (2001) QB 424 (CA) ('Source Informatics').
178 Ibid.; PRINCIPLES OF MEDICAL LAW, Supra Note 171.
184 S and Marper v. UK, (2009) 48 EHRR 50, ¶ 66-67.
185 Ibid.
186 PRINCIPLES OF MEDICAL LAW, supra note 171.
187 UK Data Protection Act, 1998 (c. 29), S.1(1) (This implementing legislation ensures compliance with the data protection principles enunciated in the Data Protection Directive).

It is dangerous to assume but that anonymization {of information|of knowledge|of information} re- moves the duty on the information controller to accommodates data confidentiality laws. In Common Services Agency v. Scottish data Commissioner,188 the revealing of data concerning the incidence of childhood leukaemia above all neighborhoods was refused by the Common Services Agency, citing a high risk of identification because of the low incidence of people laid low with the condition in those areas. The House of Lords control that the anonymised information ought to be sufficiently de-personalised before revealing,189 remitting the applying to the data Commissioner for thought in sight of the on top of call.

Under the supply scientific discipline customary, the utilization of patient-identifiable data is absolutely prohibited.190 This customary doesn't address issues over secondary uses of anonymised data, wherever the result on the information subject's non-public life is unclear. At the opposite finish of the spectrum is that the ECHR's rights-centric approach, that might have the result of imposing prohibitively high prices on today's globalized health care trade. A a lot of sensible approach would make sure that information collectors use clear strategies of assortment, process and storage.

5.3 UNITED STATES POSITION-

(The Dangers of Pharmaceutical Marketing)

The Health Maintenance Organizations Act, 1973191 was enacted with a read to stay up with the fast development within the data Technology sector. The conversion of non-public data diode to new varieties of threats with reference to the privacy of a patient. within the face of this threat, the overarching goal of providing effective and nonetheless unnoticeable health care still remains predominant. To this result, many vital federal rules are enforced. These embrace the Privacy and Security dominated underneath the insurance movableness and answerability

Act (HIPAA) 1996192 and therefore the State Alliance for eHealth (2007)193.The HIPAA privacy rules self-addressed the utilization and sequent revealing of a patient's personal data underneath varied health care plans, medical suppliers, and clearinghouses. These insurance agencies were the first agents concerned in getting a patients data for functions like treatment, payment, managing health care operations, medical analysis and subcontracting. underneath the HIPAA it's needed of insurance agencies to confirm the implementation of assorted body safeguards like policies, guidelines, rules or rules to observe and management entomb similarly as intra structure access. In the United States of America the HIPAA aims to enhance "the potency and effectiveness of the health care system by encouraging the event of a health data system through the institution of standards and needs for the electronic transmission of bound health data." 194 Patient privacy are often ensured at varied stages of data assortment, process and disclosure.195 data that's de-identified at the stage of assortment might serve the aim of protective patient namelessness. Further, the vary of excusable reasons for assortment of non-public information is also restricted to bound functions alone, like treatment. 196 so, informational privacy guarantees that the data isn't disclosed to company entities. As health care delivery systems evolve and therefore the physician-patient relationship becomes a lot of difficult, however, different interested stakeholders are currently gaining a stronger foothold within the healthcare trade.197

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188 (2008) UKHL 47.

189 See PRINCIPLES OF MEDICAL LAW, supra note 29, 693 (For the anonymised information to be considered 'personal' (per S. 1(1) of the Data Protection Act 1998), and therefore protected by the data protection principles, the data controller or CSA should be able to connect the anonymised data to any other information in its possession (like the original statistics) in order to identify the individuals involved)).

190 Health Systems Governance in Europe, supra note 30, 564.

191 Health Maintainence and Organization Act 1973, Notes and Brief Reports available at http://www.ssa.gov/policy/docs/ssb/v37n3/v37n3p35.pdf [Accessed on 14th May 2014].

192 Health Insurance Portability and Accountability Act, 1996 available at http://www.hhs.gov/ocr/privacy/hipaa/administrative/statute/hipaastatutepdf.pdf [Accessed on 14th May 2014].

193 Illinois Alliance for Health Innovation plan available at http://www2.illinois.gov/gov/healthcarereform/Documents/Alliance/Alliance%20011614.pdf [Accessed on 14th May 2014].

194 HIPAA 1996, S.261.

195 N. P. Terry, Symposium: The Politics of Health Law: Under-regulated Health Care Phenomena in a Flat World: Medical Tourism and Outsourcing, 29 W. n eng. L. Rev. 441 (2007).

196 Ibid.

197 See Jeroo S. Kotval, Market-Driven Managed Care and The Confidentiality of Genetic Tests: The Institution as Double Agent, 9 ALB. L.J. SCi. & TeCh. 1 (1998) (Managed care, a modern- day healthcare delivery structure, represents the streamlining of clinical care with a special emphasis on cost-effectiveness. A fall-out of this model of healthcare is the decreasing importance given to confidentiality of medical records, including genetic records, in favour of cutting costs and bypassing patient consent).

With commercialisation on the increase, the balance currently tilts in favor of service providers' gaining access to patient data.198

The concern over aggregation of patient data doesn't seem to be exaggerated in sight of the absence of strict needs of consent underneath the HIPAA. The marketplace for patient data is growing worldwide.199 excluding the Food and Drug Administration within the US, health insurers, researchers and drug makers square measure actively mistreatment prescription information commercially.200 it's not stunning thus that numerous state governments have didn't defend legislation preventing the sale of prescription information to pharmaceutical firms against challenges by data processing firms that such laws violate their 1st Amendment rights.201

With the Supreme Court putting down a prescription confidentiality law in Green Mountain State in early 2011, a play has been given to corporates in America to probably abuse patient disclosures.202 Green Mountain State had enacted restrictions, each on the character data|of data|of knowledge} further as on UN agency was allowed to use information for selling functions, that pharmaceutical manufacturers claimed were violations of their free speech rights.203 Since the state was unable to point out that the statute directly advanced a 'substantial government interest', however, it absolutely was command by the Court that the content-based burden in S.4631(d) of the Green Mountain State statute affected expression protected beneath the primary change, and failing the 'heightened scrutiny' take a look at.204 The Supreme Court counseled that a statute that was additional protecting of privacy or that allowable the sale of knowledge in mere a number of slender and well-justified circumstances may need survived judicial scrutiny.205

Apart from the HIPAA, around sixty laws associated with privacy within the attention sector are enacted in additional than thirty four states. These legislations are instrumental in making awareness regarding privacy needs within the attention sector and rising the potency of knowledge assortment and transfer. Similar legislative initiative is needed within the Indian context to help within the creation of a regulated and secure atmosphere touching on the protection of privacy inside the attention sector

198. See Supra Note 180.

199.M. A. Rodwin, Patient Data: Property, Privacy & the Public Interest, 36 Am. J. L. And med. 591 (2010), 592 (IMS sells data for marketing in over 100 countries and earned over $ 2 billion in 2006).

200 Supra Note 159.

201 Electronic Privacy Information Centre, IMS Health v. Ayotte, available at http://epic.org/pri-vacy/imshealth/ (Last visited February 18, 2012) (Maine, Vermont and New Hampshire are among several states that enacted laws to curtail the marketing of patient-identifiable pre- scription data).

202 Sorrel v. IMS Health Inc., 131 S. Ct. 2653 (2011).

203 Ibid, 2.

204 Vt. Stat. Ann., Tit. 18, §4631 (Supp. 2010).

205. Supra Note 18

5.4 AUSTRALIA-

Australia contains a comprehensive law that deals with sectoral laws of the proper to privacy. An change to the Privacy Act 1988206 applies to all or any attention suppliers and was created applicable from twenty first Gregorian calendar month 2001.The privacy Act includes the subsequent practices:

a. A demanding demand for consent before the gathering of health connected info
b. A provision relating to {the info|the knowledge|the data} that must be provided to people before information is collected from them
c. The concerns that need to be taken under consideration before the transfer of knowledge to 3rd parties like insurance agencies, as well as the precise instances whereby this info will be passed on
d. the main points that has got to be enclosed within the Privacy policy of the attention service providers' Privacy Policy The securing and storing of information; and
e. Providing people with a right to access their health records.

f. These provisions square measure to keep with the thirteen National Privacy207 Principles that represent the minimum standards of privacy regulation with regard to the handling of private info within the attention sector. These tips square measure informative in nature and are issued by the Privacy Commissioner in
exercise of his power beneath Section 27(1)(e)208 of the Privacy Act.
g. The Act conjointly embodies similar privacy principles that embrace a set limitation, a definitive use and purpose for the data collected, a particular set of circumstance and a longtime protocol for the revealing of knowledge to 3rd parties as well as the character and extent of such revealing, maintenance accuracy of the information collected, requisite security measures to make sure the information collected is in the least times protected, a way of transparency, responsibility and openness within the body functioning of the attention supplier and
accessibility of the patient to his own records for the aim of viewing, certification or correction.

h. Additionally, the Act includes the system of identifiers which incorporates variety allotted by the organization to a personal to spot the aim of that person's information for the operation of the organization. Further, the Act provides for namelessness whereby people have the choice to not determine themselves whereas getting into transactions with a company. The Act conjointly provides for restrictions on the transfer of private information outside Australia and establishes conclusive and demanding barriers to the extent of assortment of private and sensitive information. These principles though mistily kind of like those highlighted within the A.P. crowned head Committee report will be wont to contour the laws touching on privacy in thehealthcare sector and create them additional economical.

206.The Privacy Act 1988 available at http://www.comlaw.gov.au/Series/C2004A03712 [Accessed on 14th May 2014].
207.Schedule 1, Privacy Act 1988 [Accessed on 14th May 2014].
208.Section 27(e), Privacy Act 1988 [Accessed on 14th May 2014].

CHAPTER-VI

ELECTRONIC HEALTH RECORD SYSTEM

"Recent Technology Advances Have Made the issue of individual privacy increasingly complicated." - Jhon Thomasian

CHAPTER-VI

ELECTRONIC HEALTH RECORD SYSTEM

6.1 Health Information Systems: Past and Present

To understand the complexities of the rising electronic health record system, it's useful to grasp what the health system has been, is now, and desires to become. The medical history, either paper-based or electronic, could be a communication tool that supports clinical higher cognitive process, coordination of services, analysis of the standard and efficaciousness of care, research, legal protection, education, and certification and restrictive processes. it's the business record of the health care system, documented within the traditional course of its activities. The documentation should be genuine and, if it's written, the entries should be legible .

In the past, the medical history was a paper repository of knowledge that was reviewed or used for clinical, research, body, and money functions. it had been severely restricted in terms of accessibility, on the market to just one user at a time. The paper-based record was updated manually, leading to delays for record completion that lasted anyplace from one to six months or additional. Most medical history departments were housed in institutions' basements as a result of the burden of the paper precluded alternative locations. The MD was up to speed of the care and documentation processes and licensed the discharge of knowledge. Patients seldom viewed their medical records.

A second limitation of the paper-based medical history was the dearth of security. Access was controlled by doors, locks, identification cards, and tedious sign-out procedures for licensed users. Unauthorized access to patient info triggered no alerts, nor was it noted what info had been viewed.

Today, the first purpose of the documentation remains the same—support of patient care. Clinical documentation is usually scanned into Associate in Nursing electronic system like a shot and is often completed by the time the patient is discharged. Record completion times should meet accrediting and restrictive necessities. The electronic health record is interactive, and there area unit several stakeholders, reviewers, and users of the documentation. as a result of the govt is progressively involved funding health care, agencies actively review documentation of care.

6.1.1 Electronic Health Record (EHR)

An electronic health record (EHR) could be a record of a patient's medical details (including history, physical examination, investigations and treatment) in digital format. Physicians and hospitals area unit implementing EHRs as a result of they provide many blessings over paper records. They increase access to health care, improve the standard of care and reduce prices. However, moral problems associated with EHRs confront health personnel. once patient's health information area unit shared or joined while not the patients' information, autonomy is jeopardized. The patient might conceal info because of lack of confidence within the security of the system having their information. As a consequence, their treatment is also compromised. there's the chance of revelation of thousands of patients' health information through mistakes or thievery. Leaders, health personnel and policy manufacturers ought to discuss the moral implications of EHRs and formulate policies during this regard. The electronic medical history (EMR) is that the tool that guarantees to supply the platform from that new practicality and new services is provided for patients.

The electronic health record (EHR) is viewed by several at the same time and utilizes a bunch of knowledge technology tools. Patients habitually review their electronic medical records and area unit keeping personal health records (PHR), that contain clinical documentation concerning their diagnoses (from the MD or health care websites).

The MD, practice, or organization is that the owner of the physical medical history as a result of it is its business record and property, and also the patient owns the data within the record209. though the record belongs to the power or doctor, it's really the patient's information; the workplace of the National arranger for Health info Technology refers to the health record as "not simply a group of information that you just area unit guarding—it's a life"210. There area unit 3 major moral priorities for electronic health records: privacy and confidentiality, security, and information integrity and convenience.

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205 Odom-Wesley B, Brown D, Meyers CL. Documentation for Medical Records. Chicago: American Health Information Management Association; 2009:21.
Google Scholar.

206 Office of the National Coordinator for Health Information Technology. Guide to Privacy and Security of Health Information; 2012:5. http://www.healthit.gov/sites/default/files/pdf/privacy/privacy-and-security-guide.pdf. Accessed August 10, 2012.

6.1.2 Electronic Health Records in Asian Country

India is providing quality health care of international standards at a comparatively low value and has attracted the patients from across the world. Asian nation is currently one among the favorite destinations for the health care services. Considering speedy pace of growth of health care sector in Asian nation, Government of Asian nation in Gregorian calendar month 2013, came out with definitive tips for EHR standards in Asian nation. tips were supported the recommendations created by EMR standards committee, that was brought about by Associate in Nursing order of Ministry of Health and Family Welfare. it had been coordinated by Federation of Indian Chambers of Commerce and trade on its behalf. the rules advocate set of standards to be followed by totally different health care service suppliers in Asian nation and therefore that medical information becomes transportable and simply
transferable.211 Asian nation having a population of one.27 billion folks with solely one hundred sixty million net users maintenance of EHR could be a intimidating task, however with the interest and support of the govt. of Asian nation in its implementation, it'll successful presently.

6.1.3 Security

The National Institute of Standards and Technology (NIST), the administrative unit to blame for developing info security tips, defines info security because the preservation of information confidentiality, integrity, convenience (commonly brought up because the "CIA" triad)212. Not solely will the National Institute of Standards and Technology offer steering on securing information, however federal legislations like the insurance movableness and answerability Act (HIPAA) and also the Health info Technology for Economic and Clinical Health (HITECH) Act mandate doing thus. Violating these rules has serious consequences, together with criminal and civil penalties for clinicians and organizations.
The increasing concern over the protection of health info stems from the increase of EHRs, inflated use of mobile devices like the smartphone, medical fraud, and also the wide anticipated exchange of information between and among organizations, clinicians, federal agencies, and patients. If patients' trust is undermined, they'll not be forthright with the MD. For the patient to trust the practitioner, records within the workplace should be protected. Medical workers must bear in mind of the protection measures required to shield their patient information and also the information among their practices.

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207 E.H.R. Standards for India: GOI Report. 2013. Apr, [Last accessed on 2014 Apr 15]. Available from: http:// www.mohfw.nic.

208 National Institute of Standards and Technology Computer Security Division. An Introduction to Computer Security: The NIST Handbook. U.S. Department of Commerce. Gaithersburg, MD: NIST; 1995:5. http://csrc.nist.gov/publications/nistpubs/800-12/800-12-html/index.html. Accessed August 10, 2012.

A recent survey found that seventy three % of physicians text alternative physicians concerning work213. the way to keep the data in these exchanges secure could be a major concern. there's no thanks to management what info is being transmitted, the extent of detail, whether or not communications area unit being intercepted by others, what pictures area unit being shared, or whether or not the mobile device is encrypted or secure. Mobile devices area unit for the most part designed for individual use ANd weren't meant for centralized management by an info technology (IT)
department214. laptop workstations area unit seldom lost, however mobile devices will simply be misplaced, damaged, or stolen. Encrypting mobile devices that area unit wont to transmit tip is of the utmost importance.
Another potential threat is that knowledge is hacked, manipulated, or destroyed by internal or external users, therefore security measures and in progress instructional programs should embody all users. Some security measures that defend knowledge integrity embody firewalls, antivirus code, and intrusion detection code. no matter the sort of live used, a full security program should be in situ to take care of the integrity of the information, and a system of audit trails should be operational. Providers and organizations should formally designate a security officer to figure with a team of health info technology specialists World Health Organization will inventory the system's users, and technologies; determine the protection weaknesses and threats; assign a risk or probability of security issues within the organization; and address them. The responsibilities for privacy and security is assigned to a member of the Dr. office or is outsourced.
Audit trails. With the appearance of audit path programs, organizations will exactly monitor World Health Organization has had access to patient info.
Audit trails track all system activity, generating date and time stamps for entries; careful listings of what was viewed, for the way long, and by whom; and logs of all modifications to

electronic health records215. directors will even detail what reports were written, the amount of screen shots taken, or the precise location and laptop wont to submit missive of invitation. Alerts area unit usually set to flag suspicious or uncommon activity, like reviewing info on a patient one isn't treating or trying to access info one isn't approved to look at, and directors have the power to tug reports on specific users or user teams to review and chronicle their activity. code firms area unit developing programs that alter this method. finish users ought to be aware that, in contrast to paper record activity, all EHR activity is derived supported the login credentials. Audit trails don't stop unintentional access or revelation of knowledge however is used as a deterrent to keep at bay would-be violators.

209 Greene AH. HHS steps up HIPAA audits: now is the time to review security policies and procedures. J Am Health Inf Management Assoc. 2011;82(10):58-59. http://www.ahimajournal-digital.com/ahimajournal/201110?pg=61#pg61. Accessed August 10, 2012.

210 American Health Information Management Association. Mobile device security (updated). J Am Health Inf Management Assoc. 2012;83(4):50. http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_049463.hcsp?dDocName=bok1_04946
3. Accessed August 10, 2012.

6.1.4 Integrity and Convinience

In addition to the importance of privacy, confidentiality, and security, the EHR system should address the integrity and convenience of knowledge.

Integrity. Integrity assures that the information is correct and has not been modified. this can be a broad term for a very important thought within the electronic setting as a result of knowledge exchange between systems is changing into common within the health care trade. knowledge is also collected and utilized in several systems throughout a company and across the time of care in mobilempractices, hospitals, rehabilitation centres, then forth. This knowledge is manipulated deliberately or accidentally because it moves between and among systems.

Poor knowledge integrity also can result from documentation errors, or poor documentation integrity. a straightforward example of poor documentation integrity happens once a pulse of seventy four is accidentally recorded as forty seven. Whereas there's just about no thanks to determine this error during a manual system, the electronic health record has tools in situ to alert the practitioner that AN abnormal result was entered.

Features of the electronic health record will enable knowledge integrity to be compromised. Take, as an example, the power to repeat and paste, or "clone," content simply from one progress note to a different. This observe saves time however is unacceptable as a result of it will increase risk for patients

and liability for clinicians and organizations220,221. Another probably problematic feature is that the menu. Drop-down menus might limit selections (e.g., of diagnosis) so the practitioner cannot accurately record what has been known, and also the have to be compelled to opt for quickly might result in errors. Clinicians and vendors are operating to resolve code issues like screen style and drop-down menus to form EHRs each easy and accurate222.

Availability. If the system is hacked or becomes overladen with requests, the data might become unusable. to make sure convenience, electronic health record systems usually have redundant parts, referred to as fault-tolerance systems, therefore if one element fails or is experiencing issues the system can switch to a backup element.

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211 American Health Information Management Association. Copy functionality toolkit; 2008:4. http://library.ahima.org/29%3Cand%3E%28xPublishSite%3Csubstring%3E%60BoK%60%29&SortField=xPubDate&SortOrder=Desc&dDocName=bok1_042564&HighlightType=PdfHighlight. Accessed August 10, 2012.

212 Supra Note 198.

213 US Department of Health and Human Services. Security standards: general rules, 46 CFR section 164.308(a)-(c).

214 US Department of Health and Human Services. Technical safeguards. 45 CFR section 164.312(1)(b).

215 Supra Note 199.

6.2 RECENT DEVELOPMENTS-

The Information Technology Act, 2000, has had many amendments within the last few years that have expanded and adjusted the law ac- cording to the newest technological innovations. The IT Rules introduced in 2011,223 outline 'sensitive personal data' for the primary time in Asian country.224 The Rules stipulate that a body company collection such sensitive personal data shall acquire written consent from the supplier of same knowledge.225 This knowledge will solely be collected for a lawful purpose, that is connected to the operating of the body company. The body ought to conjointly make certain that info} supplier is formed attentive to the actual fact that such data is being collected. The supplier ought to be created attentive to the explanations that such data is being collected and of the identity of the persons United Nations agency shall receive such information.226

216 Supra Note 200.

217 American Health Information Management Association. Auditing copy and paste. J Am Health Inf Management Assoc. 2009;80(1):26-29. http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_042416.hcsp?dDocName=bok1_04241

6. Accessed August 10, 2012.

218 Ibid.

219 Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 available at http://www.mit.gov.in/sites/upload_files/dit/ files/RNUS_CyberLaw_15411.pdf (last visited February 18, 2012) ('Information Technology Rules, 2011').

There square measure only a few instances within which sensitive personal knowledge will be disclosed to a 3rd party, like once below a previous contract, the supplier has consented to such revealing
by the body company.227 Government agencies will collect such data while not previous consent, subject to the condition that the data is collected for sure mere
purposes alone which those functions square measure created best-known to the individual.228 the sole basis on that a body company in Asian nation will send knowledge to different such bodies (whether at intervals or
outside India) is that if they maintain an equivalent level of knowledge protection.229
In 2008, S.43A was introduced through the data Technology (Amendment) Act, 2008, to carry a 'body corporate' accountable for any negligence within the implementation or
maintenance of cheap security practices and procedures.230 just in case anyone had lawfully suffered a loss, the body company would be wrongfully accountable to compensate
the person by approach of damages.231 Rule eight of the IT Rules conjointly imposes a obligation on the body company to make sure compliance with practices and procedures in securing personal data. in addition, these practices should incorporate 'managerial, technical, operational and physical security management measures' that square measure equal to the type of
information assets being protected.232

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220 Information Technology Rules, 2011, Rule 3 (Sensitive Personal Data includes information relating to the physical, physiological and mental health condition, sexual orientation, medical records and history and biometric information of an individual).

221 Ibid., Rule 5; see also UK Data Protection Act, 1998, S.7(2).

222 UK Data Protection Act, 1998, §§7(1)(b)(ii) & (iii) (This provision contains a similar requirement).

223 See Information Technology Rules, 2011, Rule 6 (While prior permission of the data provider is required under this rule for disclosure of SPD, S.55 (2)(a)(ii) of the Data Protection Act, 1998, requires the consent of the data controller for either obtaining or disclosing personal data).

224 Information Technology Rules, 2011, Proviso to Rule 6.

225 Information Technology Rules, 2011, Rule 7.

226 Information Technology (Amendment) Act 2008, No. 10 of 2009, available at http://www.mit.gov.in/sites/upload_files/dit/files/downloads/itact2000/it_amendment_act2008.pdf (Last visited on February 18, 2012).

227 Ibid.

228 Information Technology Rules, 2011, Rule 8.

While the info Protection Directive specifies slim circumstances that justify the utilization of SPD, the Indian rules merely need the getting of written consent from suppliers of data. Further, the blanket provision permitting the govt to gather data while not the consent of the supplier doesn't specify the needs that its discretionary power is also used. Despite the fairly diluted commonplace of knowledge protection that has been incorporated within the IT Rules, there have still been objections from lobbyists for pharmaceutical corporations on the bottom that the restricted safeguards at intervals the foundations that stop misuse of SPD can hamper the method of knowledge assortment.

One of the most lobbyists for this position is that the International Pharmaceutical Privacy pool (IPCC), that deals with the promotion of sound policies for patient privacy in pharmaceutical corporations that have operations in Asian nation.233 Their position is that pharmaceutical corporations square measure answerable for the security of their merchandise, that need them to produce patients with placeable data in coping with reports relating to adverse reactions to medication. it's imperative, therefore, for these corporations to continue collection personal health knowledge to make sure correct application of safety measures. If the suggested smart practices for pharmaceutical corporations were to be properly enforced, such corporations would ought to keep track of data concerning patients exploitation the drug and physicians prescribing them.234 in addition, as per the regulative necessities governing US corporations in operation in Asian nation, following up with patients on the results of the drug is necessary, which needs them to retain a patient's SPD so as to perform these follow ups.235

According to the IPCC, the IT Rules might bring round a halt necessary medicine analysis that involves personal health knowledge.236 even supposing it's for the most part undisputed that consent is vital to stop physical harms, they argue that it's currently being employed to stop non-physical harms like privacy and confidentiality.237 medicine analysis for the most part consists of 'key-coded'238 knowledge. This knowledge is especially hold on so as to facilitate extra analysis purposes within the future.239 Since secondary analysis branching out from the first analysis cannot be determined throughout the primary stage,240 researchers can ought to acquire non-public medical data regarding the patients. Such data ought to, however, be de- known as researchers don't specifically have to be compelled to recognize the identity of the patient group.241 it's anticipated that the foundations could considerably hamper this method as a result of it might need corporations to urge connected with the patients to get their consent. this could even result in a discount within the range of willing patients, although they recognize that the data being provided are going to be partly de-identified. all the same the apparent connection of ethics in these things, the principles of knowledge protection and patient privacy ought to think about medicine analysis as a crucial allowable use.

Currently, the Indian lobby for pharmaco vigilance (the study and bar of adverse effects of a drug) just like the IPCC consists in the main of conglomerates within the pharmaceutical business. They advocate the utilization of partly de-identified data towards advancing medical analysis that would result in the invention of novel treatments. Their support for the utilization of pseudonymised (or partly de-identified) data might, however, result in Associate in Nursing erosion of the principles of knowledge privacy.

229 International Pharmaceutical Privacy Consortium Comments to Department of Information Technology, available at http://www.pharmaprivacy.org/download/IPPC%20Comments%20 on%20Information%20Technology %20Rules%202011.pdf (Last visited on August 17, 2012) ('IPCC Comments').

230 Ibid, 2.

231 International Conference on Harmonization (ICH) - Draft Guidance for Industry: E2D Post- Approval Safety Data Management: Definitions and Standards for Expedited Reporting avail- able at http://www.fda.gov/RegulatoryInformation/Guidances/ucm129457.htm (Last visited on August 17, 2012).

232 IPCC Comments, Supra Note 201.

233 Ibid.

234 Ibid.

The Future-

Medical practice is progressively information-intensive. the mixture of physicians' experience, data, and call support tools can improve the standard of care. Physicians are going to be evaluated on each clinical and technological competency. data technology will support the medical man call-making method with clinical decision support tools that trust internal and external knowledge and knowledge. it'll be essential for physicians and also the entire clinical team to be able to trust the info for patient care and deciding. making helpful electronic health record systems would force the experience of physicians and different clinicians, data management and technology professionals, ethicists, administrative personnel, and patients.242

235 Ibid, 4.
236 Ibid.
237 Ibid, 2.
238 Laurinda B. Harman, Electronic Health Records: Privacy, Confidentiality, and Security (Dec. 1 2019, 11:00 p.m.) https://journalofethics.ama-assn.org/article/electronic-health-records-privacy-confidentiality-and-security/2012-09.

6.3 POTENTIAL BENEFITS

The purpose of documentation through electronic media remains the same even today that is to support patient care. EHRs have several advantages over paper records. Production of legible records reduces many problems of wrong prescriptions, doses and procedure.[243] Moreover adverse drug reactions can be reduced substantially when the EHRs are connected to drug banks and pharmacies. This can be done by not permitting prescription and order for drugs for which a known adverse reaction is known for a certain patient. Easy accessibility from anywhere at any given time is also beneficial.[244] They require lessstorage space and can be stored indefinitely. They reduce the number of lost records, help research activities, allow for a complete set of backup records at low cost, speed data transfer and are cost-effective.[245,246] Hence, EHRs have been shown to improve patient compliance, facilitate quality assurance and reduce medical errors.[247]

The office of the National Coordinator for Health Information Technology (IT) refers to the health record as "not just a collection of data that you are guarding, it is life."[248] The patient owns the information in the record. The physician and the organization is the owner of the physical medical record.[249] There are four major ethical priorities for EHRS: Privacy and confidentiality, security breaches, system implementation, and data inaccuracies.

6.3.1 System Implementation

Health care organizations encounter major challenges within the course of EHR implementation these challenges lead to wasted resources, pissed off suppliers, loss of confidence by patients and patient issues of safety. the event, implementation, and maintenance of EHRs needs adequate funds and also the involvement of the many people, including clinicians, data technologists, educators, and consultants. Hospitals and health care establishments area unit creating enhancements while not vital practician engagements. several EHR implementation comes fail as a result of they underestimate the importance of 1 or additional practician to function opinion leaders for suppliers within the clinic. Thus, practician should guide colleagues in understanding their roles within the implementation and achievement their involvement in tasks as EHR choice, workflow design, and quality improvement.251

239 Sanbar SS. American College of Legal Medicine Textbook Committee. Legal Medicine. 6th ed. St. Louis: Mosby; 2004. Medical records: Paper and electronic.
240 Anderson JG. Social, ethical and legal barriers to e-health. Int J Med Inform. 2007; 76:480–[PubMed]
241 Stanberry B. Telemedicine: Barriers and opportunities in the 21st century. J Intern Med. 2000; 247:615–28.

246 Stone AA, Shiffman S, Schwartz JE, Broderick JE, Hufford MR. Patient compliance with paper and electronic diaries. Control Clin Trials. 2003; 24:182–99.
247 Lo B. Professionalism in the age of computerised medical records. Singapore Med J. 2006; 47:1018–22.
248 Office of the National Coordinator for Health Information Technology. Guide to privacy and security of health information. 2012. [Last accessed 2014 Jan 05]. p. 5. Available from: http://www.healthhit.gov.
249 Odom-Wesley B, Brown D, Meyers CL. Documentation of Medical Records. Chicago: American Health Information Management Association; 2009. p. 21.
250 Bostrom AC, Schafer P, Dontje K, Pohl JM, Nagelkerk J, Cavanagh SJ. Electronic health record: Implementation across the Michigan Academic Consortium. Comput Inform Nurs. 2006; 24:44–52.

Clinical personnel usually have very little information of the clinic's advancement and therefore the roles others play in supply. This blind spot leads to inadequate coming up with for winning implementation. while not distinguishing an identical best apply methodology to try to to the work, each user is left to struggle. Clinics ought to map and standardize their workflows before EHR choice.

When any 2 systems area unit integrated, AN interface is made. By the computer programme, we have a tendency to mean AN interface between the user and therefore the system. These interfaces area unit vital to the success of the implementation method. Interface problems area unit the best system risk as a result of these failures may be invisible at the start. Lack of general thought of users and tasks usually leads to poor computer programme. Poorly designed computer programme account for unwitting adverse consequence resulting in weakened time potency, poor quality of care and accrued threat to patient safety. Improperly designed computer programme fail to deliver the a lot of required quality of care, that cause user discontent. The faulty computer programme issue, that was little earlier on, will increase over a amount of your time that results in abandonment of EHR. Maintenance and testing of those interfaces on a routine basis is crucial in dominant this major risk. apply disruption throughout EHR implementation will negatively

impact the standard of care or endanger patient safety beside loss.252

251 Reinertsen JL, Gosfield AG, Rupp W, Whittington JW. Engaging Physicians in a Shared Quality Agenda. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2007. [Last accessed on 2014 Jan 05]. Available from: www.IHI.org .

252 Menachemi N, Ford EW, Beitsch LM, Brooks RG. Incomplete EHR adoption: Late uptake of patient safety and cost control functions. Am J Med Qual. 2007; 22:319–26.

6.1.1 Data Inaccuracies

Integrity assures that the info is correct and has not been modified. EHRs function how to enhance the patient's safety by reducing aid errors, cut back health disparities and improve the health of the general public.253 but, issues are raised concerning the accuracy and reliableness of knowledge entered into the electronic record.

Inaccurate illustration of the patient's current condition and treatment happens because of improper use of choices like “cut and paste”. This apply is unacceptable as a result of it will increase the chance for patients and liability for clinicians and organizations.254 Another feature which will cause a drag within the knowledge integrity is that the sink menu and disposition of relevant data in the trash. Such menus limit the alternatives obtainable to the practician World Health Organization in an exceedingly hurry might select the
wrong one resulting in major errors. Clinicians and vendors are operating to resolve software system issues to create EHRs each easy and correct.255

Loss or destruction {of knowledge|of knowledge|of information} happens throughout data transfer; this raises issues concerning the
accuracy of the info base as patient care selections area unit supported them.256 A growing downside is of medical fraud. This leads to the input of inaccurate data into the record of the victim. The person's insurer is beaked for medical services not provided to the particular policy holder and therefore the patient's future treatment is guided by
misinformation that neither the patient nor supplier now acknowledge.257

6.2 METHODS OF DATA SECURITY

Although establishing the confidentiality of a given piece of knowledge will usually be difficult, the conception of revealing management is supported on variety of fairly easy principles and techniques. Literature within the applied math revealing management domain typically divides this task into limitation of access (eliminating sure knowledge components from view) and applied math approaches (modifying or structuring the info to destroy unambiguously placeable characteristics). 258,259 Because we have a tendency to area unit discussing revealing management because it pertains to analysis needs, and to facilitate communication with institutional data services departments and knowledge suppliers, we've got adopted a framework that attracts heavily from the pc science domain. Thus, during this section, we have a tendency to introduce a vocabulary of strategies for reducing the identifiability of knowledge. The section “Maximizing knowledge Security in Research” can use this framework to gift a high-level recursive approach to feat helpful analysis knowledge in an exceedingly kind that minimizes the injury of unwitting revealing

253 American Recovery and Reinvestment Act, HR 1, 111th Congress, 1st Session. 2009.

254 Gelzer R, Hall T, Liette E, Reeves MG, Sundby J, Tegen A, et al. Auditing copy and paste. J AHIMA. 2009; 80:26–9.

255 Ibid.

256 North Carolina Healthcare Information and Communications Alliance, Inc. The benefits and risks of electronic health records.

257 Fouzia F. Ozair, Nayer Jamshed, Amit Sharma, and Praveen Aggarwal, Ethical issues in electronic health records: A general overview, NCBI (Dec. 1 ,2019, 11:00 p.m,) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4394583/.

258 Gonzalez M. Report on Statistical Disclosure Limitation Methodology. Statistical Policy Working Paper 22. Washington, DC: Office of Management and Budget; 1994.

259 Willenborg L, de Waal T. Statistical Disclosure Control in Practice. New York, NY: Springer-Verlag New York Inc; 1996

6.2.1 Data Exclusion

Exclusion of specific knowledge components is that the basis of most general restrictions on knowledge use. during this realm, rigorously created mixture knowledge or removal of entire records offer the very best level of confidentiality. Second to the current is individual record de-identification during which specific distinguishing fields (such as those mere by HIPAA) area unit removed. The goal is to verify that the de-identification method maximizes knowledge a specific man of science wants whereas guaranteeing enough commonality between records for obscurity.
A number of existing systems will aid during this. as an example, the conception of K-anonymity260 and the use of systems like Datafly261 (Data Privacy work, Carnegie philanthropist University, Pittsburgh, Pa) make sure that a minimum of k records in any given knowledge set area unit indistinguishable on any parameter of interest. Field masking will maintain specific aspects of the info set that area unit of analysis interest. on an analogous vein, conception Match262 (National Cancer Institute, National Institutes of Health, Rockville, Md) provides a system for de-identifying free text fields by removing words that don't match a planned set of interest words for a website. The ensuing anonymous text consists of ordinary medical terms and connexion words, with most of its analysis utility intact. notwithstanding the methodology, however, knowledge exclusion invariably destroys aspects of the first knowledge which will be helpful once creating inferences or conclusions.

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6.2.2 Data Transformation

Moving one step from absolutely the confidentiality provided by exclusion of knowledge, we have a tendency to found variety of knowledge transformation techniques that offer a applied math guarantee of confidentiality. Most secure among these area unit strategies of knowledge transformation. The common theme in these techniques is to create AN irreversible modification to the info that destroys the first values or correlations (this methodology is termed lossy, as a result of some data is irrecoverably lost within the process) whereas protective the relationships of interest.
As with knowledge exclusion, techniques exist to switch knowledge globally (as aggregation will for knowledge exclusion) or at the amount of individual parts.
Data perturbation is AN example of worldwide knowledge transformation. the concept is to preserve mixture trends within the original knowledge whereas removing or sterilization the particular knowledge. for instance, knowledge is also showing intelligence swapped between records, conserving the set of values in a very field however eliminating the precise mapping between fields of a given record, or random “noise” is also else to the information, maintaining the applied math properties of a field whereas arbitrarily sterilization actual values in any given record inside some threshold quantity. Bakken et al. gift a a lot of rigorous exploration of such techniques and plenty of of the opposite ideas mentioned during this section-7.
Hashing of individual knowledge parts involves a lossy 1-way transformation or mapping of knowledge. a straightforward hash of twenty distinctive postcode values (protected underneath HIPAA) might arbitrarily replace every distinctive postcode with a price between one and one thousand at every entry within the knowledge set. This transformation probabilistically maintains the individuality of postcode prices and therefore preserves abundant of the analysis value.

However, the finite chance of a “collision” - a pair of nada codes mapping to an equivalent new price - greatly complicates assured recovery of original values by reversing the transformation. several customary hashing algorithms exist, including
the Message-Digest algorithmic program five (MD5),263 developed at MIT, and also the Secure Hash algorithmic program one (SHA-1) developed by the National Institute for Standards and Technology.264

260 Sweeney L. K-anonymity: a model for protecting privacy. Int J Uncertainty, Fuzziness Knowledge-Based Syst. 2002; 10:557–570.
261 Sweeney L. Datafly: a system for providing anonymity in medical data. In: Lin TY, Qian S, eds. Database Security XI: Status and Prospects. New York, NY: Chapman & Hall; 1998:356–381.
262 Berman J. Concept–match medical data scrubbing: how pathology text can be used in research. Arch Pathol Lab Med. 2003; 127:680–686.

6.2.3 Data Encoding

A further step from absolute confidentiality ends up in reversible knowledge transformations, like knowledge component encoding. the concept of encoding is to require {input knowledge|input file|computer file} (plaintext) and output new knowledge (cypher text) from that the initial can't be much recovered while not the employment of specialised info external to the encrypted data (the key). a straightforward example would be to form a 1-to-1 mapping of a replacement letter for every letter within the alphabet or a code. With the mappings in hand, sick plaintext from cypher text could be a straightforward matter. while not the mapping, the matter becomes way more difficult. A key purpose here is that the strength of AN encoding theme is usually measured on the uselessness of inappropriate recovery, not the impossibility. the flexibility to interrupt the code is tied to the number of knowledge out there underneath an equivalent key, the standard of the key, and also the encoding algorithmic program itself. Details regarding cryptological techniques are printed elsewhere.

A good cryptological technique can hide all relationships between the initial text and cypher text. though valuable to protective privacy, this creates a drag for researchers, significantly in things of semi free text fields. contemplate AN analysis of health trends by leader (also a restricted field underneath HIPAA). The leader name is also encrypted with the understanding that identical names can cause identical cypher text, permitting comparison of potential leader effects while not access to the particular name. sadly, if the name is entered as free text, little variations within the entry (e.g., Wendys v. Wendy's) could lead on to substantial variations within the cypher text, creating it not possible to use the sector knowledge in AN analysis with any degree of confidence. Fixing these variations in letters used (syntax) for words with an equivalent which means could be a method known as standardization.

Cryptographic technique additionally carries some lessons to be used and dissemination of protected knowledge. maybe the foremost vital lesson is that sensible encoding isn't a substitute permanently knowledge access security. Techniques like encoding will, at best, give an extra safeguard by increasing the amount of sophistication necessary on the a part of AN unwelcome person and thereby decreasing the usefulness of trying a rear of tube. Given time, nearly each reversible cryptological technique may be compromised.

Another vital lesson from cryptography is that the price of variability in knowledge. the primary instinct of the many establishments once constructing analysis knowledge sets is to ascertain one uniform de-identified knowledge set for all researchers to access PRN. though this is often the simplest and typically the sole sensible resolution, it additionally will increase the chance of exposure. contemplate once more the leader example. One might imagine victimization data of major leaders within the space ANd an understanding of patient demographics to start sick employer info from the complete list and thereby begin breaking the cryptography theme wont to defend the data. This danger is combined if individual researchers maintain native duplicates of some or all of the master knowledge set for his or her work, and also the danger is more combined if a number of those duplicates area unit of known knowledge attributable to the requirements of a specific project.

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263 Rivest R. The MD5 message digest algorithm. Available at: http://www.faqs.org/rfcs/rfc1321.html. Accessed December 22, 2006.

264 Schneier B. Applied Cryptography: Protocols, Algorithms, and Source Code in C. 2nd ed. New York, NY: John Wiley & Sons; 1995.

6.2.4 Data Obfuscation

In the context of this discussion, we have a tendency to use the term knowledge obfuscation to denote any approach to masking knowledge that's weaker than cryptography and is utilized primarily to preserve relationships inside a knowledge set that may be destroyed by a lot of rigorous masking techniques. It ought to be noted that the term is usually used a lot of generically within the literature, though it typically relates to the trade-off between obscurity and value of knowledge. Practical use of such techniques is also most evident in interconnected numeric knowledge, like dates or addresses. for instance, medicine researchers is also curious about accessing extremely specific location knowledge to correlate health patterns with neighbourhoods, cities, or regions. However, finding clusters of poor health outcomes doesn't need information of actual patient addresses. It just needs relationships between patient addresses. Thus, information extraction for the study might translate addresses into another metric that preserves relative locations while not revealing the particular physical location. though this complicates recovery of the first data, it doesn't give the amount of structured security that coding or hashing systems do. during this example, adequate quantities of knowledge associate degreed a cognition of population trends might permit an interloper to approximate the first locations with relative ease. However, information obfuscation isn't supposed to eliminate the requirement for information access security; it merely will increase the quality of recovery and reduces the pool of would-be intruders.

6.3 DEFICIENCIES OF CURRENT REGULATION

In the u. s., current rules on the employment of protected health data for analysis functions below the insurance movability and answerability Act (HIPAA) divide anamnesis sets into three categories: known information, de-identified information, and restricted information. known information embody any information that would be employed by a recipient to unambiguously determine the person from a private patient record. Access to such information needs specific consent by study participants or a relinquishing of the consent demand by associate degree IRB. moreover, use of known information incurs varied restrictions that primarily involve the pursuit of protected health data disclosures. against this, de-identified information is information with all such identity data removed (HIPAA provides a particular list of eighteen information components that has got to minimally be removed), and this information is also used freely.

Sets containing restricted information area unit accessible solely to analysis, public health, and health care organizations. not like the opposite classes of knowledge sets, restricted information sets commit to give high-quality (of adequate detail on be helpful for analysis purposes) and accessible (able to be noninheritable and used) information for analysis, public health, and different health care–related tasks. Through a restricted information set, researchers might access information components, like date and geographic data, while not a number of the restrictions for victimisation totally known information.

Considerable analysis in privacy-preserving data processing,265,266 speech act risk assessment267,268 and information de-identification, obfuscation, and protection269,270 are often found in computing and management literature and is usually directly applicable to those medical privacy problems. additional typically, teams like government organizations unremarkably encounter

confidentiality problems within the unharness of applied math information, leading to intensive discussions regarding speech act limitation techniques.271,272 there's very little proof within the medical literature, however, to recommend that researchers exploit this flexibility in practice;

instead, they depend upon specific removal of specific distinctive information components (de-identification) or the physical security of {the information|the info|the information} infrastructure (with associate degree known data set).
The problem with this tendency toward use of either known or de-identified information is complicated. On the one hand, it provides call manufacturers the impression that de-identified information is inherently safe for public consumption. The open accessibility of enormous demographic databases across a spread of topics, however, might invalidate this assumption. for instance, students at the Massachusetts Institute of Technology were ready to re-identify thirty fifth of the records in a very 30-year span of the Chicago putting to death victims info by correlating information components with records within the social insurance Death Index, albeit each sets were public
and were thought of to be de-identified.273 Thus, the goal of de-identification might not be upheld once multiple de-identified information sets area unit accessible.
On the opposite hand, it's simple to believe that {the information|the info|the information} security restrictions on the employment of known data sets can guarantee confidentiality. sadly, the chance of unintended speech act rises with the quantity of approved users and with the quantity of duplicate information sets needed, notwithstanding the perceived level of security at every access purpose. one individual United Nations agency writes down a secret might compromise a complete information infrastructure. Indeed, the recent string of knowledge security breaches (e.g., lost and purloined tape backups and lap-tops, and mastercard and on-line banking info intrusions) shows the vulnerability of presumably secure systems.

265 Agrawal R, Srikant R. Privacy-preserving data mining. In: Proceedings of 2000 ACM SIGMOD Conference on Management of Data; May 16–18, 2000; Dallas, Tex.
266 Verykios V, Bertino E, Fovino I, Provenza L, Saygin Y, Theodoridis Y. State-of-the-art in privacy preserving data mining. ACM SIGMOD Record. 2004; 33:50–57.
267 Steel P. Disclosure risk assessment for micro data. Available at: http://www.census.org/srd/sdc/steel.disclosure\%20risk\%20assessment\%20for\%20microdata.pdf. Accessed June 2005.

268 Domingo-Ferrer J, Torra V. Disclosure risk assessment in statistical data protection. J Computational Appl Math. 2004; 164:285–293.
269 Sweeney L. Computational Disclosure Control: A Primer on Data Privacy Protection [PhD thesis]. Cambridge, Mass: Massachusetts Institute of Technology; 2001.
270 Bakken DE, Rarameswaran R, Blough DM, Franz AA, Palmer TJ. Data obfuscation: anonymity and desensitization of usable data sets. IEEE Security Privacy. 2004; 2:34–41.
271 Gonzalez M. Report on Statistical Disclosure Limitation Methodology. Statistical Policy Working Paper 22. Washington, DC: Office of Management and Budget; 1994.
272 MacNeil D, Pursey S. Disclosure control methods in the public release of micro data files of small business. Available at: http://www.amstat.org/sections/srms/proceedings/papers/1999_044.pdf. Accessed December 22, 2006.

Owing to the increasing legal and moral implications with the employment of anamnesis information, maybe the best concern is that tiny effort is applied to the documentation of knowledge security efforts once the results of associate degree analysis area unit revealed. for instance, a short review of the 2005 editions of the yank Journal of Public Health disclosed a minimum of thirty five analysis and apply articles that used doubtless protected health data (not together with studies that used in public accessible government data). Of these, just one article clearly known the safety measures used. the bulk (n = 21) either indicated IRB approval or exemption or explained why IRB approval wasn't sought-after (usually as a result of de-identified information was used). 13 articles merely expressed that IRB approval wasn't necessary. owing to the potential for speech act even with de-identified information, this lack of documentation is itself a priority. it's intelligible, however, as a result of there's a scarcity of common vocabulary for compactly describing such efforts. it's unfortunate as a result of associate degree expectation of such speech act on the a part of publications might well improve the apply of knowledge security as a full. the rest of this discussion can give a framework for wondering maximising information security. we tend to conjointly can introduce a vocabulary for describing information security efforts.

273 Ochoa S, Rasmussen J, Robson C, Salib M. Reidentification of individuals in Chicago's homicide database: a technical and legal study. Available at: http://citeseer.ist.psu.edu/ochoa01reidentification.html. Accessed June 2005.

6.4 MAXIMIZING DATA SECURITY IN RESEARCH

The previous section provides a decent foundation for discussing the confidentiality of medical information utilized in analysis studies. the particular techniques used can depend upon each the wants of a private effort and careful consultations with institutional data services departments and information suppliers. Initially, it'll take time and energy on the a part of information managers and researchers; but, a collection of normal, reusable practices ought to develop in brief order, creating the method terribly easy. Such standardization conjointly can facilitate communication of the safety infrastructure to IRBs.

What information Is Needed?

The obvious commencement in any information extraction is careful specification of the information demand. this is often customary apply in most analysis efforts, and thought ought to be offer of what records square measure necessary (i.e., solely records that meet sure criteria) and what fields of a record square measure necessary (if patient names, license numbers, and so on, aren't required, or if free text fields and pictures won't be evaluated, they ought to not be provided). what is more, as analysis progresses, access to any subsets of knowledge deemed uncalled-for upon review additionally ought to be removed. This provides a cleaner operational surroundings for analysis and minimizes injury ought to a security opening occur.

What information are often Encrypted?

Any relevant relationships discovered in reworked or obscured information would be useless while not the flexibility to recover original values. within the general case, this may need that a minimum of one field be cloaked in a very redeemable fashion. This field provides a reference by that the first record could also be discovered if necessary. This redeemable field ought to be chosen to still maximize patient confidentiality within the event of unauthorized access. for instance, Associate in Nursing encrypted study-specific patient symbol would be additional acceptable than Associate in Nursing encrypted Social Security variety. ought to Associate in Nursing interloper recover the encrypted information, exploiting the data would still need breaking the safety of the most info to realize access to the complete record.

What information ought to Be reworked or Obfuscated?

Researchers ought to currently confirm confidentiality and also the level of acceptable information loss for every field within the desired records. Those fields that solely need combination properties or probabilistic individualism ought to be cloaked by lossy transformation techniques, departure fields with confidentiality considerations self-addressed however additionally with necessary relationships preserved. it should be that any conceive to obscure this data would too complicate the study. However, some effort ought to be dedicated to considering however such information parts could also be obfuscated while not destroying relevant relationships.

Establishing the Confidentiality of Remaining information

It is clearly impractical and infrequently prejudicial to mask or modify each field in a very information set. Thus, when consistently concealment specifiable information, we have a tendency to square measure still left with variety of fields in their original type. As a final step within the construction of an enquiry information set, it should be valuable to assess, if not additional manipulate or eliminate, any remaining distinctive records. Application of techniques like K-anonymity will make sure that, though every record could also be unambiguously specifiable by use of obscured fields, no record can give a start line for breaking obfuscation techniques by standing out as distinctive within the unobscured fields.
Physical information Security and Auditing

The steps mentioned up to now could give some confidence that Associate in Nursing fortuitous information unharness won't cause important exposure of protected health data, however this is often not a reason to be casual concerning the safety of the information itself. though not explored comprehensive during this discussion, it's necessary to acknowledge that the most effective defence is nice physical information security. to it finish, customary information security practices ought to be wont to make sure that the information stay in a very secure access- restricted {storage square measurea|cargo area|cargo deck|cargo hold|hold|enclosure} which separate credentials (usernames and passwords) are given to every licensed user. This not solely prevents unauthorized access however additionally provides Associate in Nursing audit path ought to an event occur. Recognizing that security breaches square measure typically a product of social engineering (breaking system security by manipulating legitimate users—for example, by claiming that your word isn't operating and asking a legitimate user to log you in) instead of the hacking of the physical security infrastructure, a short training session on basic information security (protecting passwords, lockup workstations once not in use, and then on) could also be secure for study employees.274
Health care establishments, insurance corporations et al would require access to the information if EHRs square measure to perform as designed. The key to conserving confidentiality is to permit solely licensed people to possess access to data. This begins with authorizing users. The user's access is predicated on pre-established role-based privileges. The administrator identifies the user, determines the extent of knowledge to be shared and assigns usernames and passwords. The user ought to remember that they'll be answerable for the utilization and misuse of the data they read. they need access to the data they have to hold out their responsibilities. therefore assignment user privileges may be a major side of medical
record security.275

Although dominant access to health data is vital, however isn't comfortable for shielding the confidentiality. extra security steps like sturdy privacy and security
policies square measure essential to secure patient's data.276

6.5 CASE LAWS-

Contrary to the trend within the United Kingdom and United States, the Indian judiciary has etched out the correct to privacy as Associate in Nursing exception to the rule that allows interference by public authorities in Associate in Nursing individual's private life.277 The Supreme Court has on many occasions emphasised that the correct to privacy isn't Associate in Nursing absolute right.278 Instead, the Court has chosen to adopt a independent approach within the interpretation of the correct to privacy.279 There are instances wherever the Court has allowed a hospital to tell the patient's future married person concerning his HIV positive status.280 The principle for revealing in such cases has been the general public welfare argument that the negligent spreading of AN communicable disease is AN offence against public safety.281 This approach, that construes individual autonomy solely within the context of whether or not or not AN interface with public interest exists, differs significantly from the ECHR's rights-centric approach in **I v. Finland**.282

In breakdown the clash between the 'right to be let alone' and also the 'greater good' of the general public, the judiciary has leaned towards favouring public interest over individual privacy. 283 In **Sharda v.Dharmpal,** a husband filed for divorce on the idea that his mate was unstable.284 so as to prove this truth, the mate was compelled to bear a medical checkup. She claimed that being forced to try to to thus while not her consent would be offensive of her personal liberty. once stating that the 'right to privacy' isn't AN absolute right, the Court command that the absence of such knowledge would create it not possible to achieve a choice on the facts of the case.285

274 Rajeev Krishna, Kelly Kelleher and Eric Stahlberg, Patient Confidentiality in the Research Use of Clinical Medical Databases, NCBI (Dec. 1, 2019, 11:00 p.m.) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1829362/#r1.

275 American Health Information Management Association. The 10 security domains (updated) J Am Health Inf Management Assoc. 2012; 83:50.

276 Supra Note 255.

277 Aparna Vishwanathan, Outsourcing to India: Cross Border Legal Issues, 318 (2008).

278 See Sharda v. Dharmpal, AIR 2003 SC 3450 ("Assuming that the fundamental rights explicitly guaranteed to a citizen have penumbral zones and that the right to privacy is itself a fundamental right, such fundamental right must be subject to restriction on the basis of compelling public interest." The petitioner had had an abortion and refused to be subject to a DNA test ordered by the Court, at the instance of her husband. The Court did not recognize the petitioner's right to privacy in this matter, citing public interest); see also Selvi v. State of Karnataka, (2010) 7 SCC 263; Ms. X v. Mr. Z, 96 (2002) DLT 354.

279 See Govind v. State of Madhya Pradesh, AIR 1975 SC 1378 (The Court stated that, "The right to privacy in any event will necessarily have to go through a process of case-by-case development").

In **Shri G.R. Rawal v. Director General of revenue enhancement (Investigation),**286 the bench mentioned the orbit of S.8(1)(j) of the proper to data ('RTI') Act, 2005, that excludes revealing of 'personal information' in response to AN application.287 The Central data Commission, however, command during this case that the rule of evidence wouldn't apply wherever the larger public interest justifies revealing.288 Citing a 2007 call of the metropolis court wherever the Court allowed revealing of a prisoner's medical condition in response to AN RTI application,289 it had been any expressed that a determination of excusable revealing would be made on a case-to-case basis. whereas there could also be exceptional circumstances that justify revealing publically interest in some cases, the judicial trend ascertained in these cases has diode to a gradual erosion of the principles of private liberty, autonomy and privacy. Clearly, the Supreme Court's individual approach to process privacy doesn't give the sort of safeguards that area unit offered beneath a robust knowledge protection regime, that respects individual autonomy.

Even additional polemically, the Court has dominated that data contained in an exceedingly public record cannot be protected beneath the proper to privacy.290 Since public records may embody hospital records, jail records, and the other data collected by a state body, this ruling might have the result of bypassing any authorization demand of aggregation patient knowledge already contained publically records. it's necessary, therefore, that a comprehensive knowledge protection law is enacted to control the flow of knowledge within the hands of the State.

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280 Yepthomi v. Apollo Hospital Enterprises Ltd., AIR 1999 SC 495; Mr. 'X' v Hospital 'Z', (1998) 8 SCC 296.

281 Indian Penal Code 1860, S.269, (Non-disclosure of HIV+ status may be considered an offence, 'Negligent act likely to spread infection of disease dangerous to life').

282 See I v. Finland, Application No. 20511/03: 2008 ECHR 623 (The ECHR stated (upholding the Court's previous decision in Z v. Finland, (1988) 25 EHRR 371) that the protection of personal data, in particular medical data, is of fundamental importance to a person's enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the European Convention on Human Rights. Respecting the confidentiality of health data is a vital principle in the legal systems of all the Contracting Parties to the Convention).

283 Sharda v. Dharmpal, AIR 2003 SC 3450.

284 Ibid.

285 Ibid.

286 No. CIC/AT/A/2007/00490 (decided by Central Information Commission on March 5, 2008) ('G.R. Rawal').

287 Id. ("S.8(1)(j), therefore, excludes from disclosure an information which relates to personal information the disclosure of which

(i) has no relationship to any public activity or interest; or

(ii) would cause unwarranted invasion of the privacy of the individual").

288 Id. ("An invasion of privacy may also be held to be justified if the larger public interest so warrants").

Mr. Surupsingh Hrya Naik v. State of Maharashtra through Additional Secretary, General Administration Dept., AIR 2007 Bom 121 ("If patients are to be admitted in hospital for treatment then those employees in the hospital are duty bound to admit only those who are eligible for admission and medical treatment. The records of suc Parliament/Legislature and/or its Committees are entitled to the records even if they be confidential orpersonal records of a patient. Once a patient admits himself to a hospital the records must be availableto Parliament/ Legislature, provided there is no legal bar").

290 Mr `X' v. Hospital 'Z', (1998) 8 SCC 296.

289 h institution, therefore, ought to be available to Parliament or the State Legislature. The

CHAPTER-VII

SUGGESTIONS AND CONCLUSION

"Whatever is my right as a man is also the right of another; and it becomes my duty to guarantee as well as to possess." - Thomas Paine, Rights of Man

CHAPTER-VII

SUGGESTIONS AND CONCLUSION

7.1 SUGGESTIONS-

- It is Imperative that Privacy issues about the international flow of personal information be addressed within the best means doable. this could involve international cooperation and collaboration to deal with privacy issues as well as clear provisions and also the development of coherent minimum standards concerning international information transfer agreements. This exchange of ideas and triangular deliberation would lead to making additional economical strategies of applying the provisions of privacy legislation even among domestic jurisdictions.
- There could be a universal would like for the event of a foundational structure for the physical assortment, use and storage of human biological specimens (in distinction to the private info which will be derived from those specimens) as these ar extraordinarily necessary aspects of medical specialty analysis and clinical trials. the requirement for Privacy Impact Assessments would additionally arise within the context of clinical trials, analysis studies and also the gathering of medical specialty information.
- Further, there additionally arises the requirement for patients to be allowed to request for the deletion of their personal info once it's served the aim that it absolutely was obtained. The keeping of records for extended periods of your time by hospitals and laboratories makes no sense and may typically lead to the unauthorized access to and consequent misuse of such information.
- There could be a definitive ought to make sure the incorporation of safeguards to control the protection of patient's information once accessed by third parties, like insurance corporations. within the Indian Context still as insurance agencies typically have unrestricted access to a patient's medical records but there's a definitive lack of sufficient safeguards to confirm that this info isn't discharged to or access by unauthorized persons either among these insurance agencies or outsourced consultants
- The system of identifiers that apportion specific varietys to associate individual's information which may solely be accessed victimisation that specific number or series of numbers is incorporated into the Indian system still and may change the executive process so increasing its effectuality. this could afford people the privilege of obscurity whereas going in transactions with specific care establishments.

- An necessary means that of responding to public issues over potential unauthorized use of non-public info gathered for analysis, may be through the provision of Certificates of confidentiality as issued within the us to guard sensitive
information on analysis participants from forced speech act.291
- Additionally, it's imperative that frequent discussions, deliberations, conferences and roundtables turn up involving multiple stakeholders kind the care sector, insurance corporations, patient's rights support teams and also the government. this could aid in evolving a comprehensive policy that may aid within the protection of privacy within the care sector in associate economical and conniving manner.
- Written consent, except turning into documentary proof during a judicial trial, is additionally a confirmation of patient autonomy—the basis of recent moral philosophy. Hence, there's a necessity for a relook into the anomalies and ambiguities concerning the age of consent to endure invasive therapeutic or fact-finding procedures and clinical trials and additionally to outline the age at that a person's right to medical confidentiality begins. Further, protocols ought to be evolved to induce consent from illiterate and unsound persons and kids.

291 Guidance on Certificates of Confidentiality, Office of Human Research Protections, U.S Department of Health and Human Services available at http://www.hhs.gov/ohrp/policy/certconf.pdf [Accessed on 14th May, 2014].

7.2 CONCLUSIONS-

We have conferred a quick summary of information security techniques and also the application of those techniques to medical analysis databases. information security is of specific connexion with the proliferation of electronic medical and body records and also the ease with that such information will be exported outside of the secure institutional infrastructure. we've introduced a vocabulary for discussing these problems associate degreed have introduced an approach that researchers, data services departments, and IRB committees will use to start applying security techniques. Indeed, coordination among these teams and also the incorporation of security concerns into IRB associate degreed journal approval procedures square measure the keys to making sure continuing patient protection in an more and more digital and interconnected world.

The Right to Privacy has been embodied in an exceedingly multitude of domestic legislations bearing on the care sector. There square measure important gaps within the policy formulation that basically don't account for the information once it's been collected or its ulterior transfer. there's so associate degree close want for institutional collaboration so as to redress these gaps. Recommendations for identical are created within the report. However, for a good framework to be ordered down there's still a requirement for the State to play a lively role in enabling the engagement between totally different establishments each within the personal and property right across a large number of sectors as well as insurance corporations, on-line servers that square measure wont to harbor an information base of patient records and legal action teams that demand patient privacy whereas at identical time request to access records below the proper to data Act. The cooperative efforts of those multiple stakeholders can make sure the creation of a robust foundational framework upon that the proper to Privacy will be expeditiously made.

Regardless of one's role, everybody can want the help of the pc. making a helpful EHR system would force the experience of physicians, technology professionals, ethicists, body personnel, and patients. though EMRs provide several important advantages, the long run of health care demands that their risks be recognized and properly managed or overcome. Multiple ways square measure obtainable to scale back risks and overcome barriers within the implementation of digital health records. Leadership, teamwork, flexibility, and flexibility square measure keys to finding solutions. EMRs capacities should be maximized so as to reinforce improve the standard, safety, efficiency, and effectiveness of health care and health supply systems.

CHAPTER-VIII

SURVEY REPORT

“Getting out of the hospital is a lot like resigning from a book club. You're not out of it until the computer says you're out of it.” - Erma Bombeck

SURVEY ON DATA PRIVACY AND PATIENT CONFIDENTIALITY WITH ANALYSIS AND DISCUSSION

8.1 EXECUTIVE SUMMARY

Background: The purpose of this study was to assess the general population's knowledge/awareness about their individual data privacy and confidentiality as a patient in a doctor-patient relationship in the healthcare system.

Material and methods: This is a cross-sectional study with a total of 60 people who were surveyed without any particular/common factor being kept in mind apart from the fact that all the people surveyed were citizens of India. The survey was open to all genders, age groups and professions.

A structured questionnaire was administered to the participants and they were asked about their demographic profile, and whether they are aware of their patient data privacy and confidentiality. They were asked various questions relating to the same and at the end a small section was made in the questionnaire under the heading general information to spread awareness at the same time, through the survey, about their patient rights and data privacy.

Results: The mean age of the study population was 46 ± 17 years. Our study showed that 63.9% of patients were sure that their rights with regard to privacy are respected by their healthcare professional whereas, 29.5% were not sure and 6.6% didn't believe the same. 55.7% of patients responded that they were sometimes asked before sharing their information with others, while 24.6% responded that were always asked the same and 9.8% said they were never asked the same. Various other questions were asked to assess whether they were aware of some general information about data privacy or not, the same isexplained in the analysis of the survey. The questionnaire has been attached at the end ofthe survey as annexure-I.

Conclusion: Various surveys targeting doctors have been taken in foreign countries. But very few surveys have been taken in India and a survey targeting patients is almost zero. Itis a patient's duty to be aware about their rights too and thus, this survey aims at assessing how many people are aware about their medical rights and data privacy, and to spread the awareness about it too.

According to the survey majority of people surveyed were aware of their rights as a patient and trust their health professionals with their personal medical information. But many people were not sure and did not believe the same and I think the medical professionals should work

more on gaining the trust and spreading medical awareness about the same by conducting awareness sessions to update/ improve the knowledge of ethics among doctors and patients.

8.2 BACKGROUND AND OBJECTIVES

Throughout history, the doctor's primary ethical responsibility has been to try to to no hurt. However, with hyperbolic awareness of associate degree individual's rights doctors and patients got to return the topic of medical ethics. The elementary ideas of medical ethics include: consent, privacy and confidentiality.
Numerous studies have urged that doctors in routine clinical observe don't contemplate it necessary to get correct consent once providing patients with thorough info. Similarly, tho' respect for privacy and confidentiality has conjointly been a responsibility of doctors throughout history, it's been noted that doctors usually neglect this side of medical ethics and so, each patient ought to bear in mind concerning their personal medical information privacy and confidentiality and raise their health professionals concerning an equivalent.
Healthcare privacy may be a central moral concern involving the utilization of huge information in care, with Brobdingnagian amounts of private info wide accessible electronically and physically.

- There is that the potential for abuse by employers, insurers, and therefore the government.

- Ethicists say rules square measure required to shield individual privacy the maximum amount as attainable.

There is absolute confidence that individual privacy are compromised to a point by pc analytics creating use of Brobdingnagian amounts of private info for medical aid, analysis protocols, and insurance. Patients could don't have any plan what's through with that information, and the way they will be helped or hurt by it. Patients is injured once information concerning them square measure accustomed violate privacy. additional transparency concerning information assortment and uses, and concerning what the law will and doesn't defend, will facilitate folks create wise decisions concerning what they need to permit, and policy to be created on harms and advantages.
That is why this survey is being conducted to induce an inspiration concerning what number folks square measure privy to their rights in respect to their personal medical information privacy and confidentiality. The survey aims to assess and unfold awareness amongst the overall population concerning an equivalent.

The survey was presupposed to embody doctors within the care system too, however because of the eruption of the COVID-19 pandemic the survey was restricted to general public/patients, ensuing to that the survey sample is sixty folks because it was tougher to approach a bigger demographic, that was associate degree unpredictable downside during this survey.

8.3 METHODOLOGY

Survey Methodology-

A cross-sectional study was conducted from home, throughout April-June 2020 due to the COVID-19 pandemic irruption. sixty samples were collected through E-mail and different sharing social-media platforms, by a survey within the style of form that was structured through Google forms. The folks surveyed were every which way sent the survey and no specific gender, profession or cohort was targeted as everybody has once within their lifespan been in the capability as a patient. The folks surveyed were all Indians, all from North and South India, happiness to varied professions, aging from 17-46 years previous.

This survey was conducted to assess the extent of awareness that individuals have concerning their personal medical knowledge privacy and confidentiality rights during this technologically depended era wherever technology is taking on everything. folks got to be additional aware of their rights and personal knowledge protection.

The following ways of survey were undertaken keeping in mind the following:

❖ According to Instrumentation-

• Questionnaire- because it is right for asking closed-ended queries.

❖ According to the span of your time involved-

• Cross-Sectional Surveys- As grouping info from the respondents at one amount in time uses the cross-sectional style of survey. Cross- sectional surveys sometimes utilize questionnaires to raise a few specific topic at one purpose in time.

• Advantages of Survey Method-

• As compared to different ways (direct observation, experimentation) survey yield a broader vary of data. Surveys area unit effective to supply info on socio-economic characteristics, attitudes, opinions, motives etc. and to assemble info for coming up with product options, advertising media, commercial, channels of distribution and different selling variables.

• Questioning is sometimes quicker and cheaper than observation.

• Questions area unit straightforward to administer.

• Data is reliable.

• The variability of results is reduced.

• It is comparatively straightforward to analyse, quote and interrelate the info obtained by survey technique.

8.4 DATA ANALYSIS AND INTERPRETATION

Ques.1 By virtue of a doctor-patient relationship, you have the right to make sure that your personal medical information should not be shared with any other person without your permission.

When you provide information to your healthcare professionals, do you feel assured that your rights with regard to privacy are respected?

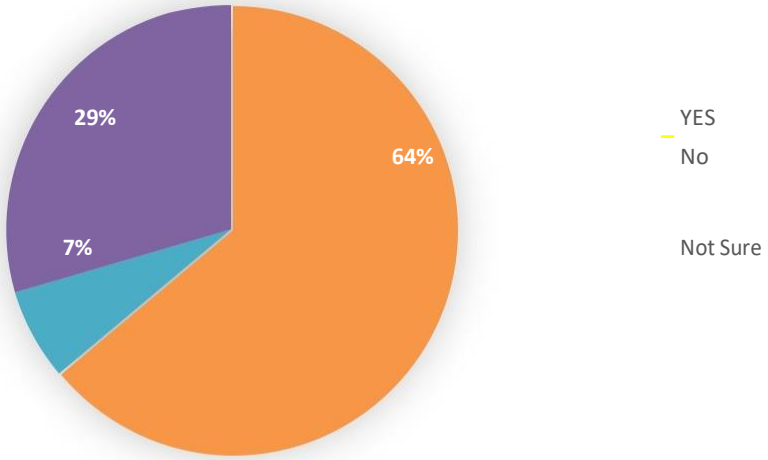


Figure-1

According to the above shown figure, 64% i.e. 38 people out of the 60 people surveyed felt assured that their rights with regards to privacy are respected, when they provide information to their healthcare professionals. Whereas, 7% i.e. 4 people were not assured ofthe same. Lastly, 29% i.e. 18 were not sure whether they feel sure that their rights with regards to privacy are respected.

It can be said that 22 people out of the 60 people who were surveyed were not sure that their privacy was respected by their healthcare professional. This proves that the healthcare

professionals should form such guidelines or spread awareness so that the patients become more sure, confident and trust their doctors with their medical privacy.

Ques.2 If your healthcare professional explain that your information needs to be shared with others in order to provide your care, are you asked if you agreed to this sharing?

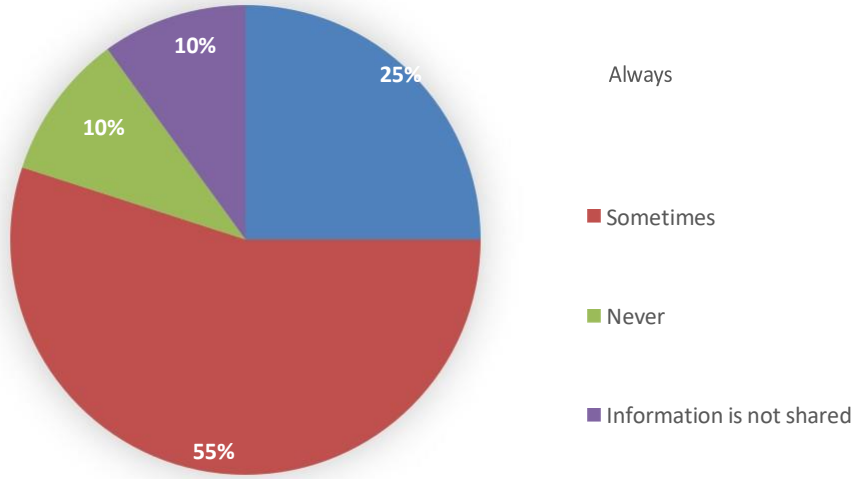


Figure-2

The above figure reflects that 25% i.e. 15 people say that their healthcare professionals always ask for their permission before sharing their personal medical information with others. While 55% i.e. 34 people are sometimes asked for their permission for such sharing. Further 10% i.e. 6 people are never asked for their permission before sharing any information. Lastly 10% i.e. 6 people said that the information is not shared thus implying that either they are not aware of the sharing or they are aware and do not allow such sharing.

This depicts that 20 people out of the 60 people surveyed were never asked for their consent before sharing their medical information with other healthcare professionals which is a breach of the duty of the doctor towards their patient.

Ques.3 When you go from one hospital to another (not transfer), do you share the information of your previous tests/medical history with the new doctor or do you have to take a new set of tests for a fresh data collection?

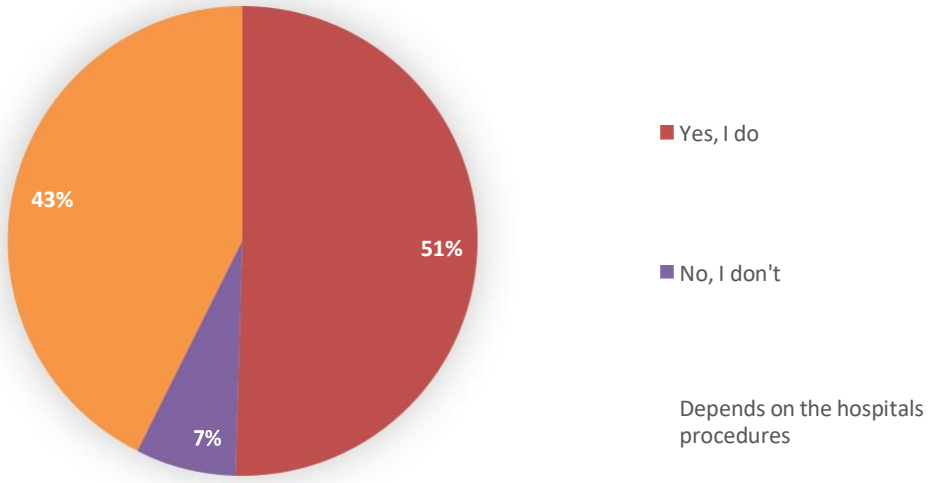


Figure-3

The above figure shows that 51% i.e. 31 people share their medical data with the newdoctor when they go from (not transfer) from one hospital to another. Further 7% i.e. 4 people said that they don't share their previous medical data and have to take new tests fora fresh data collection and when they go from one hospital to another. Lastly, 43% i.e. 26 people said that it depends on the hospitals procedures whether they have to share their medical history with a new doctor when they go from one hospital to another.

This depicts that more people voluntarily share their previous medical history with a new doctor, but what they need to understand is that if a person goes (not transfers) from one hospital to another they should get new tests and form new set of data from the starting as it helps get a full knowledge about the patients current health situation and thus work efficiently and more accurately as every doctor works differently.

Ques.4 Have you ever heard any of the medical personnel's (doctors/nurses) discuss about any other patients medical information that might sound sensitive, in an open space in the hospital?

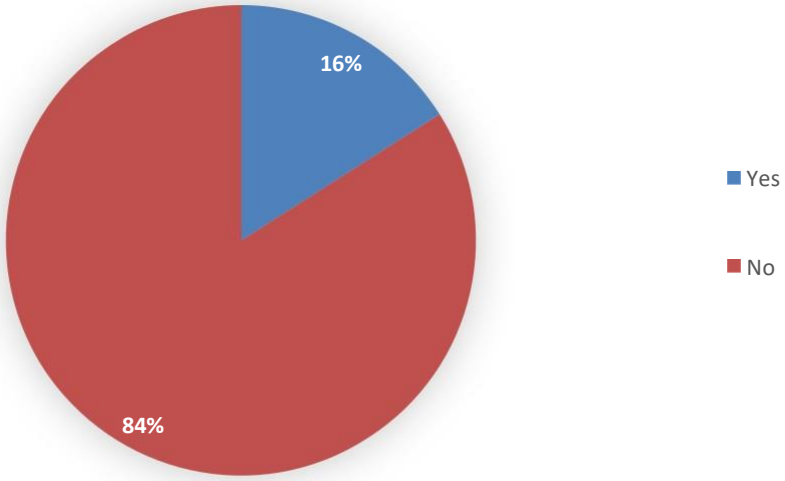


Figure-4

The above figure shows that 16% i.e. 10 people said that they have heard medical personnel's discuss about any other patients sensitive personal medical information, in an open space in the hospital. Whereas 84% i.e. 51 people said that they have never heard the same.

This depicts the carelessness on part of some of the medical personnel's who have the duty to not share someone's personal sensitive medical information with another person without their consent and that too never in an open space in the hospital where any stranger can hear the same.

Ques.5 Has it ever happened with you or any of your family members that any of your personal medical data was stated incorrect or went missing from the hospital?

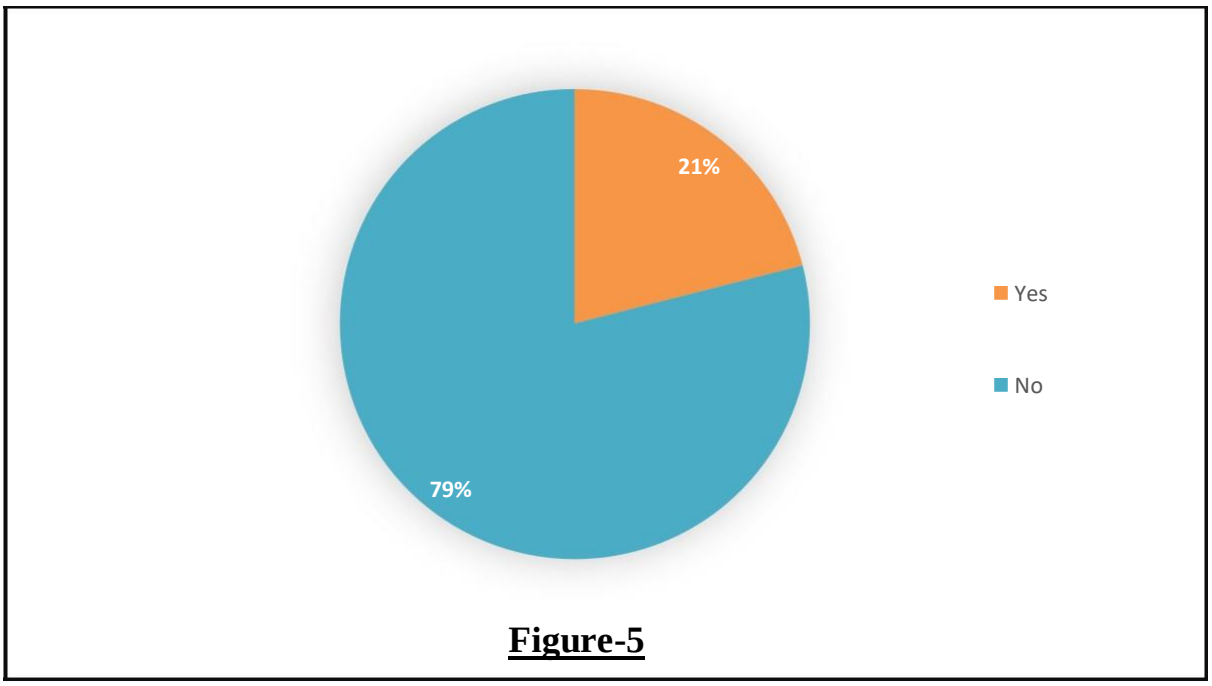


Figure-5

From the above figure we can analyse that 79% i.e. 48 people have never faced the problem of their medical data being incorrect or missing from the hospital. Whereas, 21% i.e. 13 people have faced the problem which shows the inadequacy of the hospitals in taking care of their patients personal medical information and which could result in greater damage if in wrong hands.

Ques.6 Do you think that a doctor can deny his duty of patient confidentiality in the name of public interest or if it required to be disclosed by law?

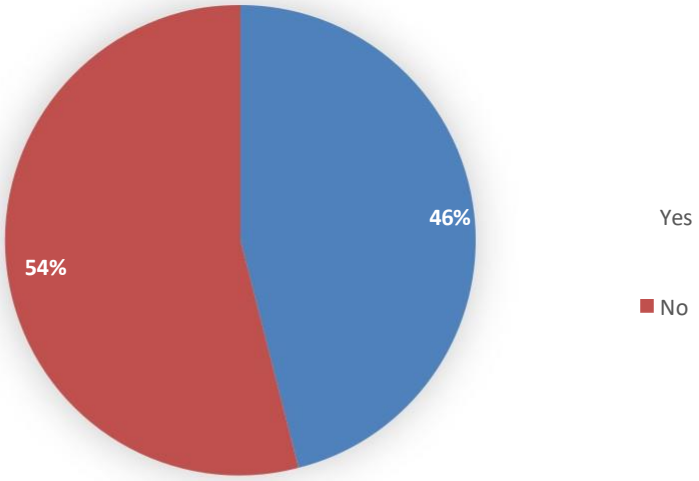


Figure-6

The above figure shows that 46% i.e. 28 people feel that a doctor can deny his duty of patient confidentiality in the name of public interest or if it required to be disclosed by law. Whereas 54% i.e. 33 people believe that a doctor cannot deny his duty of patient confidentiality in the name of public interest or if it is required to be disclosed by law.

This shows the lack of awareness amongst people about the fact that according to law it is a doctor's duty to deny his duty of patient confidentiality in the name of public interest or if it required to be disclosed by law as public interest supersedes personal interest.

Ques.7 In the case of a minor (below 18 years of age) or a mentally disabled adult who do you think the doctor is obligated to share/disclose sensitive medical information/reports with about such a patient?

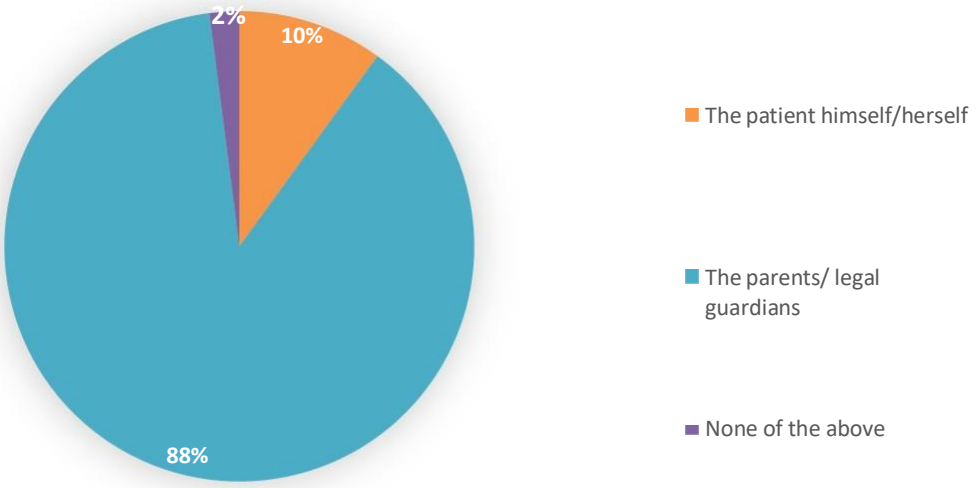


Figure-7

The above figure reflects that 88% i.e. 54 people believe that in the case of a patient who is a minor (below 18 years of age) or a mentally disabled adult the doctor is obligated to share/disclose sensitive medical information/reports with the parents or legal guardians of such a patient. Whereas, 10% i.e. 6 people believe that the information can be shared with the patient himself/herself. Lastly 2% i.e. 1 person says that the doctor should not disclose such a patient's medical information with any of the abovementioned people.

This depicts that 12% people are not aware that only parents or legal guardians of a minor or a disabled adult have the access to their personal medical information. The doctor is obligated to inform the parents/legal guardian of such people as they are said to not have the mental capacity to give consent and know the difference between right or wrong and therefore need a sane elder person to tell them the same.

Ques.8 In case of a deceased person (dead), do you think a doctor still have to maintain his duty of patient confidentiality?

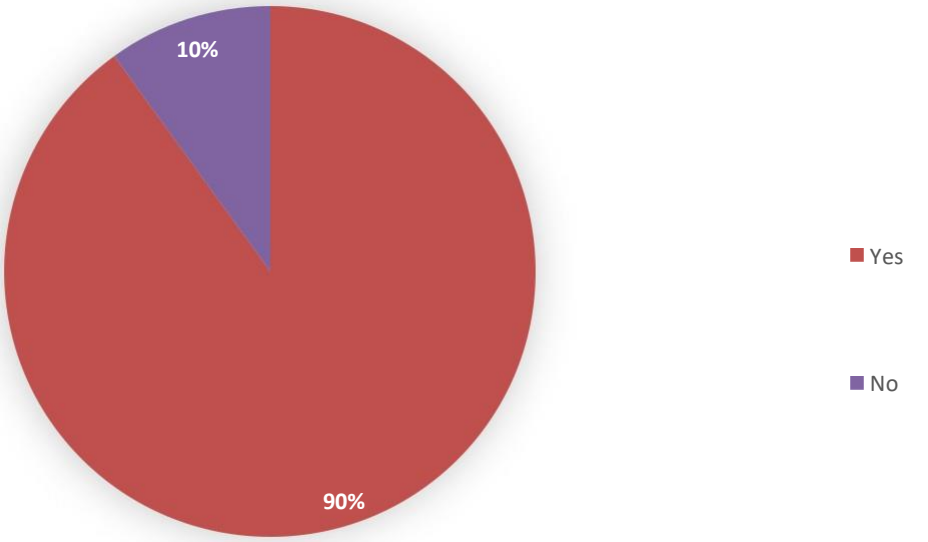


Figure-8

The above figure reflects that 90% i.e. 55 people think that even after a patient's death he still have to maintain his duty of patient confidentiality. Whereas 10% i.e. 6 people think that after a patient's death the doctor does not have to maintain the deceased persons medical confidentiality.

This shows that 6 people are not aware that a doctor's duty towards his deceased patient does not end with the death of the patient and he is obligated for the same.

Ques.9 Do you think patient confidentiality applies to spouses (Husband & Wife)?

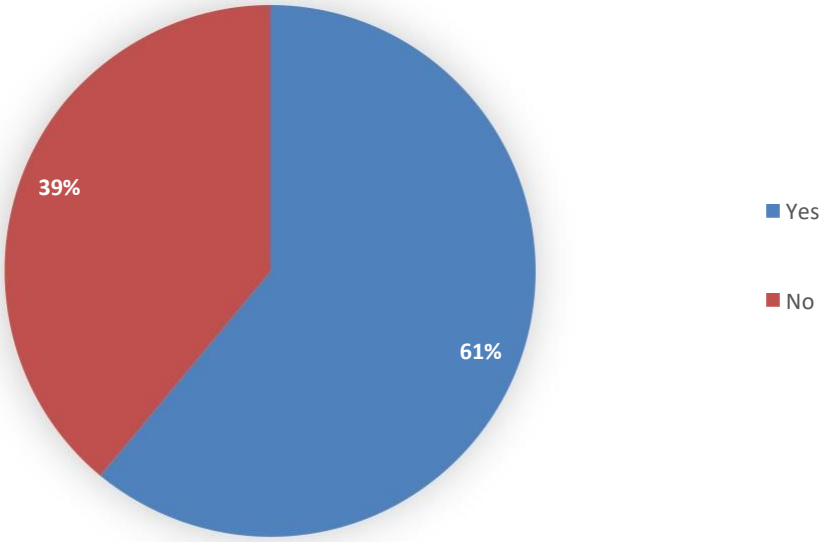


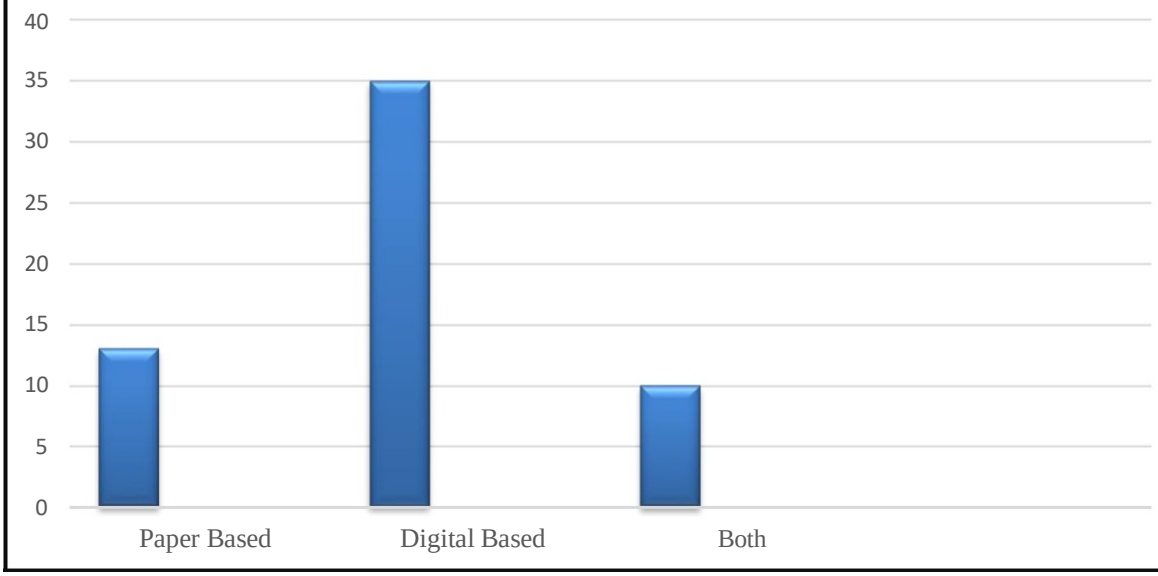
Figure-9

The above figure reflects that 61% i.e. 37 people think that the patient confidentiality applies to spouses. Whereas 39% i.e. 24 people think that the patient confidentiality does not apply to spouses.

The correct answer is that patient confidentiality does not apply to spouses as it is believed that marriage is a sacred sacrament and the 2 married people have to live together forever and after marriage are dependent on one another. After marriage the legal guardian of a wifeis her husband therefore a doctor have to discuss any patients personal health issue with the legal guardian.

Ques.10 Do you prefer physical (paper-based) or electronic (digital-based) form of medical data storage. State the reason for the same.

Figure-10



The above figure reflects that out of the 60 people who were surveyed, 35 people prefer Digital based form of data storage. Whereas 13 people prefer Paper based form of data storage. Further 10 people preferred both the forms of data storage.

Reasons for Digital storage were-

- Easy accessibility and storage for longer period of time.
- Environment friendly.
- More secure as it is encrypted and password protected.
- Less chances of damage or getting lost.

Reasons for Paper storage were:

- In case of mistakes one can correct it.
- Digital based might get hacked whereas the chances of misplacing a paper are quite rare.

Reasons for both were:

- Paper with digital backup to avoid the risk of data being locked for any reason as medical history should be stored in a way to use for any uncertainty in the future.

GENERAL INFORMATION-

Patient Rights

By virtue of a doctor-patient relationship, you have the right to make sure that your personal medical information should not be shared with any other person without your permission. You have the right to inform your doctor about the same.

Doctors Duty

In the name of public interest or if is required by any law, are the only two options by virtue of which a doctor can deny his/her duty towards a patients confidentiality. The doctor would have to prove the same.

Minor or Mentally Disabled Patients Privacy

In the case of a minor (below 18 years of age) or a mentally disabled adult the doctor is obligated to share/disclose sensitive medical information/reports with the parents and if not parents, then legally designated guardian of such a patient.

Dead Patients Right

In the case of a deceased person (dead), a doctor still have to maintain his duty of patient confidentiality as such a disclosure might affect the lives of the family members or the people connected to him, after his death.

Husband/Wife

Patient Confidentiality doesn't apply to husband and wife as marriage is a very sacred relation between a man and woman who have to live together for the rest of their lives and they have the right to know about each other’s personal medical information.

Ques.11 Was this questionnaire helpful in any way?

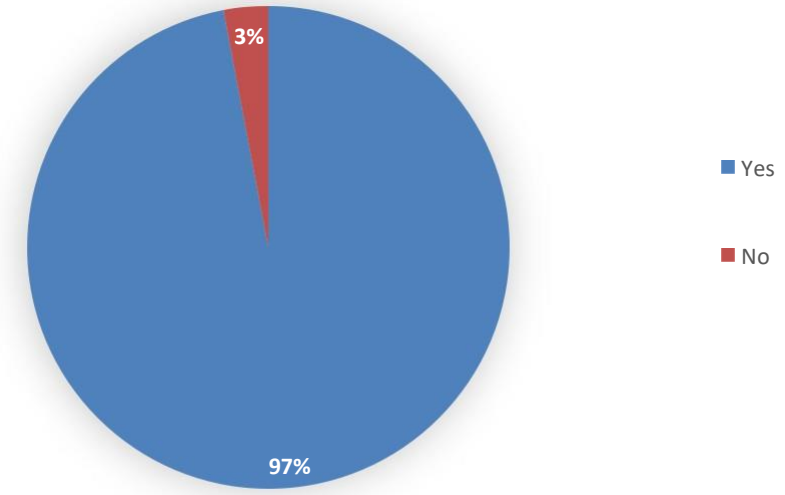


Figure-11

After a small column about general information to spread more awareness on this topic people were asked whether they found this questionnaire helpful or not, to which 97% i.e. 59 people said that they found it helpful and 3% i.e. 2 people did not find it helpful.

8.5 CONCLUSIONS AND LIMITATIONS

This survey has several limitations. First, the sample size was only 60 people because of the Covid-19 pandemic which made it harder to survey more people. Doctors were supposed to be added to the survey too but due to the pandemic their availability was restricted. The respondents were selected randomly and in small number which is why only people from certain states were included because of which the survey could not be applicable on the whole of India.

Even with the noted limitations, the survey findings shed light on an important issue. It provides preliminary data that reinforce anecdotal evidence that show concerns for patient confidentiality. Though many people who were surveyed were aware of their rights some of the people were not aware of the general information about their medical data privacy and patient confidentiality which is a bigger issue as one goes from urban to rural areas. Therefore, awareness building should be conducted for doctors as well as patients toimprove and refresh their knowledge of ethical principles.

8.6 RECOMMENDATIONS

- There are no reported surveys within India, to the author's knowledge that has studied the views of patients regarding the awareness and knowledge of the general population about their data privacy and patient confidentiality in their capacity as patient, therefore more research and ways to spread awareness about the topic should be done.
- Current guidelines and policies should be changed keeping in mind the patient's rights and practical's of the various ethical principles about patient confidentiality bedone to see their applicability in real life.

8.7 ANNEXURE-I

Patient Confidentiality Questionnaire

One of the most basic rights that a patient has is the right to privacy. Patients have the right to decide to whom, when, and what extent their private individually identifiable health information is disclosed. This information includes but is not limited to medical diagnosis, treatment plans, prescriptions, health insurance information, genetic information, clinical research records, and mental health records. All of these come under data privacy and patient confidentiality in healthcare system.

* Required

1. Name *

2. Age *

3. Profession *

4. City / State *

Patient Questionnaire

This questionnaire is made with the motive of data collection and spreading awareness about patient's right to confidentiality.

5. Ques.1 When you provide information to your healthcare professionals, do you feel assured that your rights with regard to privacy are respected? *

Mark only one oval.

- Yes
- No
- Not Sure

6. Ques.2 If your healthcare professional explain that your information needs to be shared with others in order to provide your care, are you asked if you agreed to this sharing? *

Mark only one oval.

- Always
- Sometimes
- Never
- Information is not shared

7. Ques.3 When you go from one hospital to another (not transfer), do you share the information of your previous tests/medical history with the new doctor or do you have to take a new set of tests for a fresh data collection? *

Mark only one oval.

- Yes, I do
- No, I don't
- Depends on the hospitals procedures

8. Ques.4 Have you ever heard any of the medical personnel's (doctors/nurses) discuss about any other patients medical information that might sound sensitive, in an open space in the hospital? *

Mark only one oval.

Yes

No

9. Ques.5 Has it ever happened with you or any of your family members that any of your personal medical data was stated incorrect or went missing from the hospital? *

Mark only one oval.

Yes

No

10. Ques.6 Do you think that a doctor can deny his duty of patient confidentiality in the name of public interest or if it required to be disclosed by law? *

Mark only one oval.

Yes

No

11. Ques.7 In the case of a minor (below 18 years of age) or a mentally disabled adult who do you think the doctor is obligated to share/disclose sensitive medical information/reports with about such a patient? *

Mark only one oval.

The patient himself/herself

The parents / If not parents, then legally designated guardian None of the above

12. Ques.8 In case of a deceased person (dead), do you think a doctor still have to maintain his duty of patient confidentiality? *

Mark only one oval.

Yes

No

13. Ques.9 Do you think patient confidentiality applies to spouses (Husband & Wife)? *

Mark only one oval.

Yes

No

14. Ques.10 Do you prefer physical (paper-based) or electronic (digital-based) form of medical data storage. State the reason for the same. *

_____

General Information

Patient Rights

By virtue of a doctor-patient relationship, you have the right to make sure that your personal medical information should not be shared with any other person without your permission. You have the right to inform your doctor about the same.

Doctor's duty

In the name of public interest or if is required by any law, are the only two options by virtue of which a doctor can deny his/her duty towards a patients confidentiality. The doctor would have to prove the same.

Minor or mentally disabled patient's privacy

In the case of a minor (below 18 years of age) or a mentally disabled adult the doctor is obligated to share/disclose sensitive medical information/reports with the parents and if not parents, then legally designated guardian of such a patient.

Dead patient's right

In the case of a deceased person (dead), a doctor still have to maintain his duty of patient confidentiality as such a disclosure might affect the lives of the family members or the people connected to him, after his death.

Husband/wife

Patient Confidentiality doesn't apply to husband and wife as marriage is a very sacred relation between a man and woman who have to live together for the rest of their lives and they have the right to know about each other's personal medical information.

15. Was this questionnaire helpful in any way? *

Mark only one oval.

- Yes
- No

BIBLIOGRAPHY

Books-

- Blackstone's: Statutes on Medical Law, 401-410 (Edited by Anne E. Morris and Michael A. Jones, 7th Ed., Oxford University Press, 2011).
- Jo Samanta, Medical Law, 70-81 [Ash Samanta (Contributor), 2nd ed., Macmillan Law Masters, 2015].
- Lyon's: Medical Jurisprudence and Technology,101-102 (11th Edition, Revised by Dr. T.D. Dogra, Professor and Head of Dept. of Forensic Medical & Toxicology, AIIMS, New Delhi, Delhi Law House Publication).
- Michael Davies, Textbook on Medical Law, 29-55 (2nd Ed. Paperback 1998).
- Shaun D. Pattinson, Medical Law and Ethics, 199-240 (3rd Ed., Sweet and Maxwell, 2011).

Journals-

- Indian Journal of Medical Ethics.
- Indian Journal of Urology.

Statutes-

- Epidemic Diseases Act, 1897.
- European Convention on Human Rights and Biomedicine.
- Health Insurance Portability and Accountability Act, 1996.
- Health Maintenance Organizations Act, 1973.
- Indian Contract Act, 1872.
- Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 (Code of Ethics Regulations, 2002).

- Indian Penal Code, 1860.
- Information Technology (Amendment) Act 2008.
- Information Technology Rules, 2011.
- Immoral Traffic (Prevention) Act 1956.
- Insurance Regulatory and Development Authority (Third Party Administrators) Health Services Regulations, 2001.
- Medical Termination of Pregnancy Act, 1971.
- Medical Termination of Pregnancy Regulations, 2003.
- Mental Health Act, 1987.
- National Policy for Persons with Disabilities, 2006.
- Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act, 1994.
- Privacy and the Right to Information Act, 2005.
- The Criminal Law (Amendment) Act, 2013, (Amendments to Criminal Procedure Code, 1973).
- The Constitution of India.
- The EU Data Protection Directive.
- The Indian Majority Act, 1875.
- The IRDA (Sharing Of Database for Distribution of Insurance Products) Regulations 2010.
- The Prisons Act, 1894.
- The Privacy Act 1988.
- The Protection of Children from Sexual Offences Act, 2012.
- The Right to Information ('RTI') Act, 2005.
- The UK Data Protection Act, 1998.

Sites-

- Journalofethics.ama-assn.org.
- www.ncbi.nlm.nih.gov.
- www.legalservicesindia.com.
- www.researchgate.net