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Editorial

The NHS Turns 75

The fifth of July this year marked the 75th anniversary of the establishment of the National Health Service, better known as the NHS, in the UK on this day in 1948. Prior to the Second World war (1939-45) accessibility to health care in the UK depended greatly upon where one lived. In the countryside most large villages would have a General practitioner, and sometimes a cottage hospital which would have a small number of beds. Treatment would be by payment, although in many areas a form of contributory health insurance was in place. Most towns and cities would have a Royal Infirmary, or a Free hospital; the local surgeons and physicians would have Visiting attachments, usually honorary. In addition there would often be a private hospital. In many towns the local municipal council ran the hospital service. The inadequacies of the system were the backdrop to Dr. A. J. Cronin's novel, The Citadel. Published in 1937 it led to public criticism of the provision of healthcare.

The outbreak of war brought multiple challenges: many doctors volunteered for military medical service, a large number of beds were required for military casualties evacuated from the various overseas battlefronts, and civilian casualties from bomber raids had to be treated, in addition to the usual ill health. By 1938 it was realised that war was coming, so the Ministry of Health formulated the Emergency Hospital Service, whereby the running of 2,378 hospitals across the UK was directly financed by the government to provide for wartime needs.

In November 1942 the British government published the *Social Insurance and Allied Services* report. This was drafted by the economist William Beveridge, so is often referred to as the Beveridge report. It contained proposals for social reforms to be introduced after the war ended. These led to the creation of the British welfare state, of which the National Health Service was an integral part. The passage of the National Health Service of 1946, and the actual start of the NHS on July 5th 1948, were directly due to the efforts of Anuerin Bevan, the Minister of Health in the post war Labour government of Clement Attlee. The founding principles of the NHS were that it was to be funded out of general taxation not national insurance, and services would be provided by the same doctors and the same hospitals. The services were provided free at the point of use, and everyone was eligible for care.

As of October 2021 there were 1,229 NHS hospitals in the UK. In November 2022 there were 1,32,900 doctors, 3,50,600 nursing staff (including midwives and health visitors) and 36,600 managers in the NHS out of a total workforce of 1.26 million. The NHS is the largest public sector employer in the UK, and also in Europe.

The increase in life expectancy, and the increasing cost of modern medical care have put severe strain on the funding of the NHS. Over the years there have been cycles of staff shortages, with the domestic shortfall usually met by recruitment of doctors and nurses from outside the UK. It is estimated that 67% of doctors are British, while 16% are Asian, with the single largest group coming from India. Over the years a large number

of Indian doctors have benefitted from working and training in the UK.

Universal health coverage of a uniform standard, free at the point of delivery, still remains a dream in India, although the recent introduction of government backed health insurance cards by both Central and State governments have arguably improved access to healthcare for the common man. Whether anything akin to the best of the NHS will ever be possible remains to be seen.

The Ethics and Medical Registration Board of the NMC has just gazetted a new set of regulations dealing with Professional Conduct, along with several guidelines. We are reprinting the English version for the convenience of all faculty and students. The remaining guidelines will appear in the next issue.

Ranjan Raychowdhury, Executive Editor; Professor, Department of ENT & Head Neck Surgery, RKMSP, VIMS

Original Article

Association of Vascular Endothelial Growth Factor and Oxidative Stress in Type 2 Diabetes in Population of West Bengal

Priyanka Biswas[1], Anumoy Mukherje[2], Baidyanath Pal[3], Debasish Maji[4], Madhusnata De[5]

The work was done between the periods of 2015-2019.

Abstract :

Type 2 Diabetes Mellitus (T2DM), the most frequent subtype of diabetes, comprises a complex heterogeneous group of metabolic diseases characterized by high levels of blood glucose (hyperglycaemia) and impaired insulin action and/or insulin secretion due to β cell dysfunction. Increasing evidence in both experimental and clinical studies suggest oxidative stress (OS) plays a major role in the pathogenesis of T2DM and its complications. In a physiological condition appropriate levels of Reactive Oxygen Species (ROS), generated either in restricted amounts or in a transient fashion, are essentially required to promote physiological angiogenesis and homeostatic maintenance of healthy vasculature. Uncontrolled continuous ROS production ultimately contribute to pathology and causes tissue damage. One of the most important proangiogenic factors is Vascular Endothelial Growth Factor (VEGF) which plays a key role in diabetic endothelial dysfunction, which ultimately leads to pathogenesis of vascular complications. Therefore, we aimed to investigate the association between antioxidant status and VEGF levels in plasma that may lead to vascular complications. A case-control study of one hundred and fourteen patients with T2DM (n=114) and thirty three control subjects (n=33) were screened from different areas of West

which gives rise to a risk o
damage (retinopathy, nephropathy and neuropathy) [Orasanu et al., 2009]. It is associated with reduced life expectancy, significant morbidity due to specific diabetes related microvascular complications, increased risk of macrovascular complications (ischaemic heart disease, stroke and peripheral vascular disease), and diminished quality of life [WHO, 2016].

According to the Diabetes Atlas (7th edition), the global prevalence of diabetes is estimated at 415 million (8.8%), which is expected to rise to 642 million in next 25 years [IDF, 2015]. India is being referred to as the 'diabetic capital of the world' [Joshi et al., 2012]. About 31% of the population of West Bengal is suffering from T2DM [Shashank et al., 2012]. Factors associated with the pathogenesis of long-term diabetic complications are multifactorial, although persistent hyperglycemia (glucotoxicity) seems to be a key mediator. At least three distinct metabolic pathways seem to be involved in the pathogenesis of long-term complications; it is likely that all of them play a role in a tissue-specific manner [Kumar et al., 2018]. The main consequences of these pathways lead to the formation of oxidative stress (OS) which appears to be the major underlying cause of diabetic complications.

OS-dependent angiogenesis is an important contributor to the progression of cancers and chronic diseases. One of the most important proangiogenic factors is Vascular Endothelial Growth Factor (VEGF). OS induces the over expression of the VEGF gene in T2DM and leads to the development of late diabetic complications.

In this study, the relationship between the VEGF level in plasma and stress level [level of malondialdehyde (lipid peroxidation) and activity of superoxide dismutase, catalase and glutathione peroxidase] were examined. To the best of our knowledge, no previous study was found in the literature which sought to investigate the relationship between VEGF expression and antioxidant status in the context of T2DM and its complications in the population of West Bengal. Therefore, we aimed to investigate the association between antioxidant status and VEGF level in plasma that may lead to vascular complications.

Materials and Methods

Study Setting and Subjects :

A case control study was conducted, between 2015 and 2019, on all cases with Type 2 Diabetes Mellitus (T2DM) who were referred to the Department of Endocrinology and Department of Surgery of Ramakrishna Mission Seva Pratishthan, Kolkata, India. A total of one hundred and fourteen patients with T2DM (n=114) and thirty three control subjects (n=33) were included in the study. The participants were age and sex matched. The patients were confirmed T2DM by impaired fasting glucose test (> =126 mg/dl) and oral glucose tolerance test (> =200 mg/dl) [WHO, 2005]. The controls had a history of having normal glucose metabolism, and were without hypertension, hyperlipidemia, and other metabolic syndromes. We excluded patients who had fever, acute and chronic infections, malignancy, acute and chronic nephritis, cirrhosis, and congestive heart failure. All the patients were in stable conditions during assessment. Detailed personal histories were collected from the participants with the help of a questionnaire.

This study was approved by the Institutional Ethical Committee on 10th May, 2016 (Reg No. ECR/62/Inst/WB/2013 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945) and was conducted in accordance with the principles of the Declaration of Helsinki. All procedures were done with the informed consent of participants. The methods in this study were performed in accordance with the relevant guidelines and regulations.

Collection of peripheral blood :

Peripheral blood samples were collected by

venepuncture both from T2DM patients and control subjects. Blood samples were collected in EDTA vacutainer and stored at 4ºC for experimental work.

Biochemical Study :

Estimation of Plasma Malondialdehyde (MDA)**:** Plasma was separated from blood samples by centrifugation at 2500 rpm for 20 minutes. Plasma was then further analysed for malondialdehyde (MDA) level estimation. Plasma MDA was measured spectrophotometrically by the modified method of Okhawa et al. (1979).

Estimation of Superoxide Dismutase (SOD): The activity of SOD was assayed by the method of Kakkar et al. (1984).The assay of SOD is based on the inhibition of formation of NADH-phenazine methosulphate-nitroblue tetrazolium formazon. The colour formed at the end of the reaction can be extracted into butanol and measured at 560nm. SOD activities are expressed as units/ml [Magnani et al., 2000].

Estimation of Catalase : The activity of catalase was assayed by the method of Sinha (1972) using dichromate-acetic acid reagent. The chromic acetate formed was measured at 620 nm. Catalase activities are expressed as units/min/ml. Estimation of Glutathione Peroxidase (GPX): For analysis of GPX activities, hemolysate of washed erythrocytes was used. The glutathione peroxidase activity was measured by the modified method of Paglia and Valentine (1967) using tert-butyl hydroperoxide as a substrate. Activity of GPX1 was calculated using the molar extinction coefficient of NADPH 6220 M^{-1} cm^{-1}. One unit of GPX1 (U) is defined as 1 µmol of NADPH oxidized to NADP per min. GPX activities are expressed as units/ml.

Measurement of plasma VEGF : Peripheral blood samples were collected from the patients and healthy volunteers to determine the plasma VEGF level. Plasma was separated from peripheral blood samples by centrifugation at 2500 rpm for 20 minutes. The plasma VEGF concentration was determined using Human VEGF (Vascular Endothelial Growth Factor) enzyme-linked immune sorbent assay kit (Fine Test, China) in Bioradi Mark^{TM} Microplate Reader. Intra - assay precision was <8% and Inter – assay precision was <10%. The detection range of the assay was 0-2000 pg/ml.

Statistical analysis :

All variables were expressed as mean ± SE (standard error). Statistical analyses were done using Independent 't' test and Chi Square test. Statistical significance was defined as P=0.05. All statistical analyses were performed by using statistical software Statistical Package for Social Sciences (SPSS).

Results :

Comparisons between control and T2DM cases in terms of Glucose concentration following Impaired Fasting Glucose and Oral Glucose Tolerance Test have been graphically presented in Figure 1a and 1b respectively.

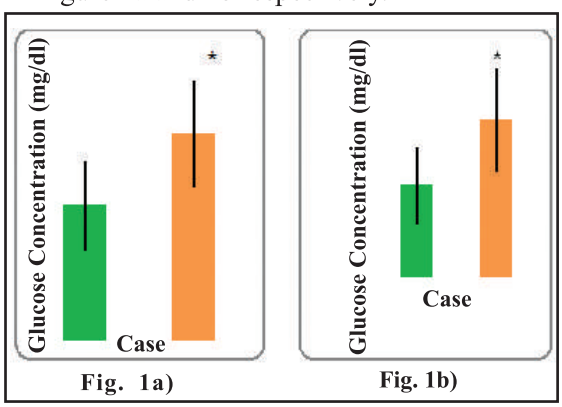


Figure 1 Comparison between Control and T2DM cases in terms of Glucose concentration following Impaired Fasting Glucose and Oral Glucose Tolerance Test

Comparison between Control and T2DM cases in terms of HbAIC (%) has been presented graphically in Figure 2.

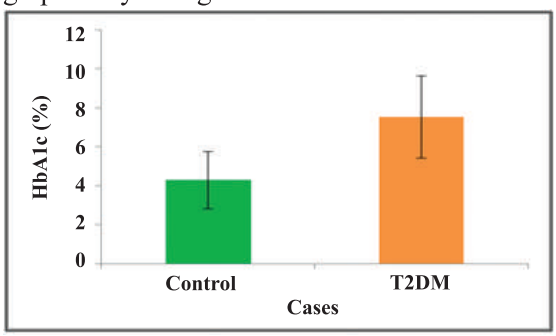


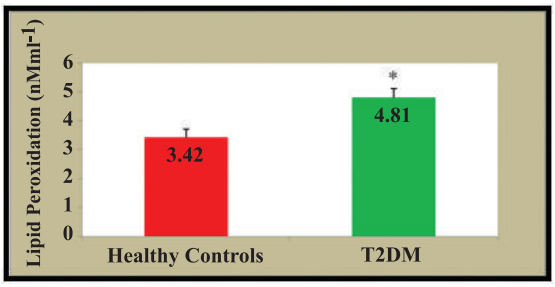
Figure 2 Comparison between Control and T2DM in terms of HbAIC (%)

Biochemical Study :

Lipid Peroxidation In Studied Cases

Quantitative in vitro lipid peroxidation level in whole blood was estimated. Plasma malondialdehyde (MDA) level was measured for assessing lipid peroxidation level. The data were statistically analyzed by Independent 't' test to compare healthy controls and patients. The study showed significantly elevated plasma MDA level ($p<0.05$) was found in T2DM patients (4.81 ± 0.31 nM ml^{-1}) compared to control subjects (3.42 ± 0.29 nM ml^{-1}). peroxidation can be a useful biomarker for OS for the risk of T2DM progression and its complications.

Fig. 3 Lipid Peroxidation level in the Studied Cases (a) Between healthy controls and T2DM (b) Between healthy controls and different groups of T2DM based on complications.

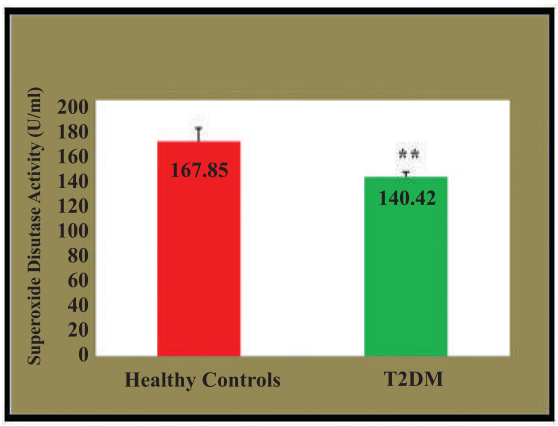


*** Statistically significant at p<0.05 (Independent *'t'* test)**
**** Statistically significant at p<0.001 (Independent *'t'* test)**

Superoxide Dismutase (Sod) Activity In Studied Cases

Quantitative in vitro Superoxide Dismutase activities in whole blood were estimated. The data were statistically analyzed by Independent 't' test to compare healthy controls and patients. In the present study, significant decrease in SOD activity ($P=0.001$) was found in T2DM patients (140.42 ± 3.72 U ml^{-1}) compared to control subjects (167.85 ± 10.56 U ml^{-1}).

Fig. 4 Superoxide dismutase activities in the Studied CasesBetween healthy controls and T2DM

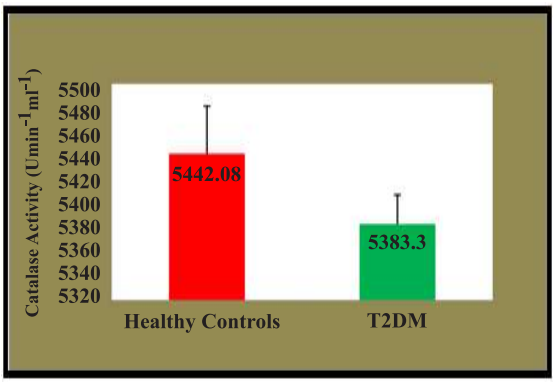


*** Statistically significant at p<0.05 (Independent *'t'* test)**
**** Statistically significant at p<0.001 (Independent *'t'* test)**

Catalase Activity in Studied Cases

Catalase is an enzyme in protecting the cell from oxidative damage by ROS. Quantitative in *vitro* Catalase activities in whole blood were estimated. The data were statistically analyzed by Independent *'t'* test to compare healthy controls and patients. Our study revealed that catalase activity had diminished in T2DM patients (5383.30 ± 24.59 U $min^{-1}ml^{-1}$) compared to control subjects (5442.08 ± 39.38 U $min^{-1}ml^{-1}$).

Fig. 5 Catalase activities in the Studied Cases Between healthy controls and T2DM

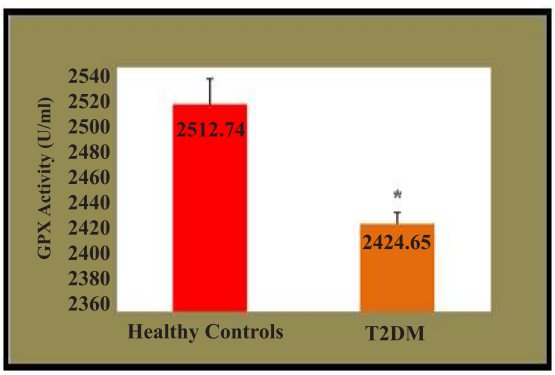


Statistically insignificant at p>0.05 (Independent *'t'* test)

Glutathione Peroxidase (Gpx) Activity In Studied Cases

Quantitative in vitro GPX activity in whole blood was estimated. A comparison between healthy control subjects and T2DM patients in respect to GPX activity was done. The data were statistically analyzed by Independent 't' test to compare healthy controls and patients. Present study found that GPX activity was significantly lower (P< 0.05) in T2DM patients (2424.65±8.53 U ml^{-1}) than control subjects (2512.74±18.96 U ml^{-1}).

Fig. 6GPX activities in the Studied Cases Between healthy controls and T2DM



*** Statistically significant at p<0.05 (Independent *'t'* test)**

**** Statistically significant at p<0.001 (Independent *'t'* test)**

VEGF Estimation in Studied Cases

VEGF levels in plasma was compared between healthy controls and T2DM. Elevated VEGF level was found in T2DM patients compared to healthy controls and it was found statistically significant (P< 0.001).

Table 1. VEGF level in Plasma in Studied Cases

Group	VEGF Level in plasma (pg/ml) (mean±SE)	p-value
Healthy Controls	317.9±12.9	-
T2DM	526.8±34.3	0.000**

*** Statistically significant at p=0.05 (Independent *'t'* test)**

**** Statistically significant at p=0.001 (Independent *'t'* test)**

Discussion :

The number of diabetes cases worldwide has increased according to the estimation by the International Diabetes Federation, of which T2DM constitutes approximately 90% to 95%. Up to 80% of mortality with T2DM is directly associated with vascular complications. Many experimental and clinical studies have shown that oxidative stress is an important factor in the pathogenesis of both Type 1 and Type 2 Diabetes Mellitus. At least three distinct metabolic pathways seem to be involved in the pathogenesis of long-term complications; it is likely that all of them play a role in a tissue-specific manner [Kumar et al., 2018]. One of the factors is the process of non-enzymatic glycation of proteins, lipids and nucleic acids, with subsequent formation of advanced glycation end products (AGEs) [Brownlee, 1994]. Other factors are activation of protein kinase C and disturbances in polyol pathway. One of the main consequences of these adverse actions is the formation of oxidative stress (OS). Oxidative stress represents

an imbalance between the production and manifestation of Reactive Oxygen Species (ROS) especially free radicals and a biological systems ability to detoxify the reactive intermediates or to repair the resulting damage. The increase in the level of ROS in diabetics could be due to their increased production and/or decreased destruction by enzymatic catalase and superoxide dismutase antioxidants. DM causes oxidative degradation of lipids in cell membranes resulting in cell damage. Lipid degradation leads to increased susceptibility to lipid peroxidation.

OS-dependent angiogenesis is an important contributor to the progression of cancers and chronic diseases. VEGF is the most potent and primary endothelial specific angiogenic growth factor, both in physiological and pathological conditions. VEGF signaling is ultimately required for normal vascular development and homeostasis, but it is also actively engaged in tumor progression by promoting growth of tumor vasculature [Shibuya et al., 2008]. This signaling pathway often seems to be affected by ROS. Thus, the reciprocity between oxidative stress and angiogenesis has been centered on the VEGF signaling pathway. VEGF appears to play a central role in mediating microvascular pathology in late diabetic complications.

Antioxidants are agents that protect, prevent, or reduce the extent of oxidative damage to biomolecules (proteins, lipids, and nucleic acids) causing cellular dysfunction and alteration in lipid profile leads to increased susceptibility to lipid peroxidation. These agents may be enzymatic, non-enzymatic, or metal chelators. The enzymatic antioxidants include superoxide dismutase (SOD), catalase and glutathione peroxidase (GPx). SOD, a copper, zinc and manganese-containing enzyme, reacts with superoxide radicals to form hydrogen peroxide, which is then converted to water by GPX (a glutathione-dependent selenoprotein), or catalase, a heme enzyme. The present study indicates that the diminished activity of SOD, catalase and GPX in the plasma of T2DM patients might be due to antioxidant depletion. Presence of ongoing free radical activity and breakdown of protective antioxidant species occurs due to the depletion of the antioxidant. The reduction in the activity of SOD may be due to excessive oxygen radical production from autooxidation of glucose, glycated proteins and glycation of antioxidative enzymes, which limit the capacity to detoxify oxygen radicals. Diminished catalase activity may result in increased damage to various proteins, lipids and DNA [Tiwari et al., 2013; Asmat, Abad and Ismail, 2016]. Our study found that GPX activity was significantly lower ($P< 0.05$) in T2DM patients than control subject. This suggested that the antioxidant enzyme production is affected in T2DM patients leading to higher risk of cell organ damage [Chandrika et al., 2017]. The low activity of GPX could be directly explained by the low content of GSH found in patients with T2DM, since GSH is a substrate and cofactor of GPX. Enzyme inactivation could also contribute to low GPX activity. GPX is a relatively stable enzyme, but it may be inactivated under conditions of severe oxidative stress. Inactivation of this enzyme may occur through glycation governed by prevailing glucose concentration [Rahbani-Nobar, 1999]. Alteration in GPX activity found in our study can be considered an adaptation of antioxidant defense against increased production of ROS. Reduced GSH level in red blood cells reflects generalized decrease in intracellular content of this compound. Thus the obtained results show that T2DM patients have lower GSH content in

erythrocytes than the healthy control group. The trend found in this study is consistent with the report of Aaseth and colleagues, who found reduced levels of GPX in erythrocytes of subjects with poorly controlled T2DM [Aaseth & Stoe-Birketvedt, 2000, Gonzalez et al., 2016, et al., 2016, Ines G & Elhadj-Ahmed, 2017]. Our result indicates that patients with T2DM have lower activity of GPX, which increases the susceptibility of cells to the damaging effects of ROS.

The observed increase in MDA levels, as shown in Figure 3, may be due to the enhanced production of lipid peroxides and their release in circulation that leads toincreased oxidative degradation of lipid in cell membranes (lipid peroxidation) which is responsible for T2DM progression and its complications and can be a risk factor for development of cancer. The increase in levels of MDA shows that free radicals are formed disproportionately in T2DM by glucose degradation, non-enzymatic glycation of proteins, and the subsequent oxidative degradation, which may contribute to the development of complications in diabetic patients. Late diabetic complications are developed with increased activity of free radical – induced lipid peroxidation and accumulation of lipid peroxidation products. Enhanced MDA level is a prognostic factor for the risk of T2DM progression and its complications. Hence, increased lipid peroxidation with reduced antioxidant activity can be a useful biomarker for OS leading to the risk of T2DM progression and its complications.

In this study, the relationship between the plasma VEGF level and progression of T2DM complications was examined; it was more prevalent in T2DM patients compared to the controls. Table 1 shows the elevated VEGF level in T2DM patients compared to healthy controls and it was found statistically significant. Elevated VEGF level in T2DM leads to the risk factor for the progression of late diabetic complications.

To the best of our knowledge, this is the first cohort study to investigate the association between oxidative stress and VEGF expression in diabetic patients leading to the risk of vascular complications.

Conclusion :

We observed that alteration in VEGF level can be a risk factor for the presence and severity of vascular complications in diabetic patients which was supported by elevated oxidative stress and a strong correlation existed between them. This suggests that it may be a reliable biomarker for evaluating the development and progression of vascular complications.

Acknowledgment :

We would like to acknowledge the Secretary, Ramakrishna Mission Seva Pratishthan, colleagues of our Department and all the patients who participated in this study.

Author Statements :

Ethical approval : This study was approved by the Institutional Ethical Committee on 10th May, 2016. Reg No. ECR/62/Inst/WB/2013 issued under Rule 122DD of the Drugs & Cosmetics Rules 1945.

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Conflict of interest: None declared.

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Review Article

Hearing Loss and Its Impact on Quality of Life : An Overview

Ranjan Raychowdhury/ChatGPT

Editors note : *This paper was generated using the free ChatGPT program, as a demonstration of what AI is capable of*

Abstract :

Hearing loss is a common condition that affects millions of people worldwide. It can occur at any age and can have a significant impact on an individual's quality of life. The aim of this paper is to provide an overview of hearing loss and its impact on the quality of life of affected individuals. We will discuss the different types of hearing loss, their causes, diagnosis, and treatment options. Additionally, we will review the effects of hearing loss on communication, social interaction, emotional well-being, and cognitive function.

Introduction :

Hearing loss is a common sensory impairment that affects millions of people worldwide. It is estimated that over 466 million people worldwide have disabling hearing loss, and this number is expected to increase to 900 million by 2050 (1). Hearing loss can be temporary or permanent and can affect one or both ears. It can occur at any age, but it is more prevalent among older adults.

The impact of hearing loss on an individual's quality of life cannot be overstated. Hearing loss can affect communication, social interaction, emotional well-being, and cognitive function. It can lead to feelings of isolation, depression, and anxiety. The aim of this paper is to provide an overview of hearing loss and its impact on the quality of life of affected individuals.

Types of Hearing Loss :

Hearing loss can be classified into three main types: conductive, sensorineural, and mixed hearing loss.

Conductive hearing loss occurs when sound waves are not able to reach the inner ear due to a blockage or obstruction in the outer or middle ear. This type of hearing loss is usually temporary and can be caused by factors such as ear infections, earwax buildup, or abnormalities in the ear structure.

Sensorineural hearing loss occurs when there is damage to the inner ear or the nerve pathways that transmit sound from the inner ear to the brain. This type of hearing loss is usually permanent and can be caused by factors such as aging, exposure to loud noise, and genetic factors.

Mixed hearing loss is a combination of conductive and sensorineural hearing loss.

Causes of Hearing Loss :

The causes of hearing loss can vary depending on the type of hearing loss. Conductive hearing loss is usually caused by factors such as ear infections, earwax buildup, or abnormalities in the ear structure. Sensorineural hearing loss is usually caused by factors such as aging, exposure to loud noise, and genetic factors.

Other factors that can contribute to hearing loss include ototoxic medications, head injury, tumors, and certain medical conditions such as diabetes.

Diagnosis of Hearing Loss :

The diagnosis of hearing loss typically involves

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a hearing test conducted by an audiologist. The audiologist will test the individual's ability to hear different frequencies and volumes of sound. Based on the results of the hearing test, the audiologist can determine the type and severity of the hearing loss.

Treatment of Hearing Loss :

The treatment of hearing loss depends on the type and severity of the hearing loss. Conductive hearing loss can often be treated with medications, surgery, or the removal of earwax or other obstructions. Sensorineural hearing loss is usually treated with hearing aids or cochlear implants. Mixed hearing loss may require a combination of treatments.

Impact of Hearing Loss on Quality of Life :

Hearing loss can have a significant impact on an individual's quality of life. It can affect communication, social interaction, emotional well-being, and cognitive function.

Communication :

Individuals with hearing loss may have difficulty understanding speech, especially in noisy environments. This can lead to frustration, isolation, and a decreased quality of life.

Review Article

Live Surgery Workshop on Application of Ilizarov Fixator at Ramakrishna Mission Seva Pratishthan

Satyaki Ghosh

Introduction :

Magic they call it, some say Miracle!

Ilizarov frames provide a versatile fixation system for the management of bony deformities, fractures and their complications. The frames give stability, soft tissue preservation, adjustability and functionality allowing bone to realise its full osteogenic potential. It is important that we have a clear and concise understanding of the Ilizarov principles of deformity correction to best make use of this fixation system.

Keeping in focus the ardent need to somewhat fullfill the need of understanding the basics of Ilizarov principles amongst young post-graduates and enthusiastic orthopaedicians the Orthopaedics department of the Pratishthan arranged a Live Surgery workshop on 24th December 2022. The aim was to learn the basics from the master himself, Prof. Dr. D. K. Jha with assistance from West Bengal Orthopaedic Association (WBOA).

Dr. Chandrachur Bhattacharya was the organising secretary & the joint secretary Dr. Anirban Bhattacharya was the key person for planning & arrangements.

Various Faculties from the state was invited, Dr. A. K. Bera being the chief guest. Present & previously-attached faculties blessed the programme with their valuable presence.



(Pre-conference preparation : From left Dr. P. K. Pujari, Dr. A. Bhattacharya, Dr. D. K. Jha, Dr. B. Gayen discussing method of deformity correction with students with help of saw bone models)

Junior Resident, Department of Orthopedics, RKMSP, VIMS

History of Ilizarov method :

Prof. Gavriil AbramovichIlizarov started his career treating a number of patients in Western Siberia, who had returned from World War II having sustained fractures. During the 1950s, Ilizarov began experimenting with external fixation designs; in 1954, he successfully treated his first patient, a factory worker with a tibial non-union. He experienced excellent results, significantly reducing healing time. During this time, he also, by chance, discovered distraction osteogenesis for bone lengthening when he observed callus formation in a patient who had mistakenly distracted his frame instead of compressing it.

In 1968, Valery Brumel, an Olympic champion high jumper at the 1964 games, visited Ilizarov in Kurgan. He had suffered a compound fracture of his distal tibia in 1965 and, despite 20 operations over 3 years, had developed an infected non-union and a significant leg-length discrepancy. His resultant surgery was a widely publicised success and gained Ilizarov recognition within the Soviet Union.

In 1980, Carlo Mauri, a well-known Italian journalist and explorer, was treated in Kurgan. Mauri had suffered a distal tibial fracture 10 years previously during an Alpine accident. Whilst on an Atlantic exploration, his old leg wound re-opened and a Russian team physician advised him to consult Ilizarov in Kurgan. On his return to Italy, the surgeons were amazed by the healing that had occurred in this long-standing non-union and, the following year, arranged for Ilizarov to present his findings at the AO Conference in Bellagio. News of this advance was quick to travel and very soon was being adopted by surgeons both sides of the Atlantic.

Basic science and principles of distraction osteogenesis :

During distraction, **regenerate bone** arises between the entire cross-sections of each distracted bone surface with a central radiolucent fibrous interzone comprising of type I collagen. New bone trabeculae form directly from this central collagen zone extending to both bone surfaces. It is orientated **parallel to the distraction force** and surrounded by blood vessels. Following distraction, these microcolumns consolidate and rapidly remodel to form a structure similar in composition to that of the host bone, a process called **consolidation**.

Up to 10% lengthening is well-tolerated by muscle, but substantial histopathological changes occur after lengthening of 30%. Nerves, arteries and veins had histological evidence of temporary degenerative changes but these disappeared 2 months after lengthening.

Short-term changes in articular cartilage of the knee in tibial lengthening of rabbits showed that the cartilage underwent histopathological changes, including reduced thickness of the hypertrophic and proliferative zones.

Mechanical principles of the Ilizarov method:

Circular fixators are comprised of several components, the most fundamental being rings and connecting rods. Full rings provide the most rigidity; partial rings and arches are particularly helpful when working near joints and allow wound access needed after trauma.

Bony stability is essential for osteogenesis and is dependent on the stability of the external frame. Frame stability is greatly impacted by the ring properties; rings of large diameter are less stable than smaller rings. Reducing ring diameter by 2 cm increases axial frame stiffness by 70% therefore, the smallest diameter ring that will fit

the extremity should be used. A general guideline is to leave 2-cm space between ring and skin circumferentially to allow for possible limb swelling. Distance between the rings will also affect stability; rings that are far apart and connected with long rods will be less stable. In order to minimise the unsupported length between rings, additional connecting rods or an intermediate free ring secured in the mid-portion of the long rods should be used.

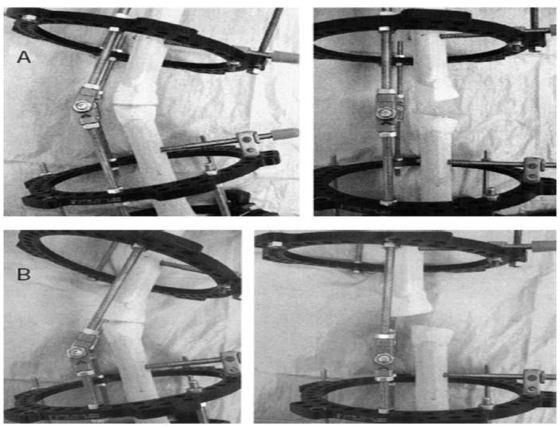
The stability of the ring is further increased by using two rings instead of one for each bone segment, thus controlling both near and far ends of each bone segment. A minimum of four connecting rods between the rings and at least two points of fixation or wires per ring are required. Atrophic non-unions require double ring blocks to increase the stability of the construct. In hypertrophic non-unions, one ring block per segment would be sufficient as long as no deformity correction is needed. Lengthening frames usually gain and sustain additional stability from distraction forces needed to overcome the soft tissue envelope; therefore, one ring per segment with multiple wires in different planes would be used. The ring frame supports and stabilises the underlying bone through the use of transfixion wires and half pins. Frame stability increases with increasing wire diameter and tension, the use of more wires per ring, placing wires on opposite sides of the ring and inserting wires in different planes. Increasing crossing angles of wires to 90° provides maximal stability and crossing angles of less than 60° may allow the bone to slide along the wires requiring the use of opposing olive wires or the addition of a half pin. Olive wires provide an important buttress effect in the correction of angular deformity.

A thorough knowledge of the cross-sectional anatomy of the extremity is necessary to avoid neurovascular injury. If under a general anaesthetic, the patient should not receive paralytic agents as this will mask the important signs of muscle flickering when a motor nerve is irritated. It is important to minimise the heat generated during wire drilling to prevent bone and soft tissue necrosis. Wire ten-sioning greatly enhances the rigidity of the wire and stability of the frame.

Smooth wires are typically tensioned to 130 Nm as tension beyond 155 Nm will cause stretching and plastic deformity of the wire.

Wires crossing an angle of less than 60° should be tensioned simultaneously to ensure equal tension across both wires.

Deformity correction can be achieved using hinges on the connecting rods but this requires very accurate frame construction (to avoid lengthening, compression or translation. As a consequence, hexapod systems, such as Taylor-spacial frames, have become popular). By placing the hinge on the bisector line and off the cortex correcting the deformity will cause distraction at the bone ends (A). Positioning the hinge off the bisector will cause a translational deformity (B)



(Placement of hinge in a Ilizarov frame)

Ilizarov external fixators in Deformity correction :

Deformity assessment requires a thorough knowledge of normal anatomical alignment and rotation. Usually, the contralateral limb can be used as a reference, and radiographs are a routine part of deformity and leg-length discrepancy investigation. A full-length, standing, anteroposterior radiograph of both lower limbs, using blocks under the short leg to level the pelvis, are taken. Anteroposterior and lateral radiographs will guide management and provide a template for pre-operative planning.

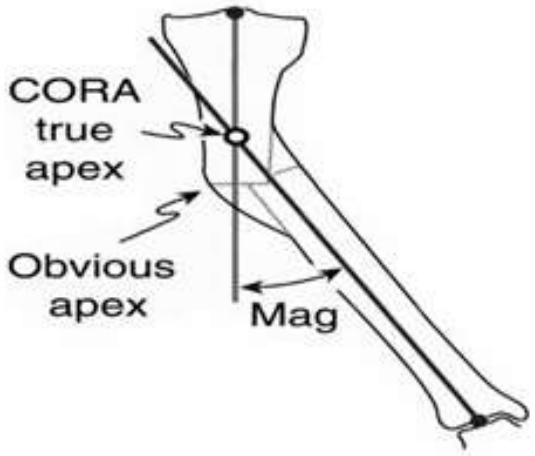
To correct the leg-length discrepancy, a corticotomy is performed, the bone is exposed and the periosteum incised and elevated paying careful attention to preserve its integrity. Using a drill, multiple drill holes are made circumferentially through the cortex and the corticotomy is completed using an special osteotome that doesn't harm periosteum, called as corticotome.

For tibial lengthening, the suggested site of corticotomy is at the junction between proximal metaphysis and diaphysis, distal to the tibial tuberosity. Femoral lengthening corticotomies are usually just distal to the lesser trochanter.

To correct angular deformity, an awareness of the normal mechanical axis is required. This represents a line drawn from the centre of the femoral head to the centre of the ankle mortice. The location of this line in relation to the knee joint defines the mechanical axis deviation, normally 0-8 mm medial to the centre of the knee.

Any deviation from this value denote varus or valgus deformities. The site of the deformity must be identified and mid-diaphyseal lines can be drawn on a radiograph on either side of a deformity. The point at which these lines bisect is the centre of rotation and angulation (CORA), and the angle between these lines is the magnitude of the deformity.

A corrective osteotomy at this site will allow angular correction without translation. In cases where there is length discrepancy and angular deformity, correction can be made at one level, the CORA, if bone regeneration potential is good. Alternatively, a double level osteotomy may be performed, one at CORA for deformity correction and one at the advised level for lengthening.





Dr. Amiya Kumar Bera demonstrating multi-planar deformity correction

Use of Ilizarov fixator in infected non-union:

This particular use of Ilizarov ring fxator was discussed in minute detail during the live surgery that was being broadcasted from operating roomto Gahanananda Hall where 48 delegates were present.

In the operation theatre a 24 year old male with right tibia infected non union was undergoing Ilizarov ring fixation application. The operating surgeons was Dr. P. K. Pujari (Head of the department), Dr. Chandrachur Bhattacharya & Dr. B. Gayen.

Simultaneously each operative steps were being discussed by faculties of the Pratishthan.



Dr. Kanailal Jana discussed the importance of Refreshening of non-union fracture ends

Freshening / Refreshening is removal of infected implants, unhealthy dead necrotic tissues by multiple drilling, nibbling or reaming till punctuate bleefing spots are noted from non union fracture ends and form a healthy vascular bed. It is needed to reinitiate the process of biological bone healing .

Dr. Bikramjit Gayen explained how to perform partial fibulectomy and he suggested to perform fibulectomy in its middle 1/3rd, as the lower 1/3rd is important to maintain ankle mortise & upper 1/3rd has nutrient artery & other important neurovascular structures namely the Common peroneal artery.

Dr. Jayabrata Ghosh discused method of Acute docking.

He explained how the ends of the two main bone fragments were exposed. The fragment which was pre-operatively marked out as a peg was sculpted into an invaginating end (cortical peg). The other bone end was converted into a receptacle for this peg (medullary hole). The two ends were fitted into each other (peg in hole).

He also mentioned how autologous bone graft can be used in docking site to further improve chances of union.

In the patient being operated, excised portion of fibula was used as bone graft at docking site.

Dr. Atanu Chatterjee discussed how to perform

corticotomy without damaging periosteum & endosteum.

He emphasized importance of being careful while executing corticotomy on posterior cortex if tibia.

Dr. Jha, Dr. Bera & Dr. Partha Pal discussed distraction osteogenesis in great detail and how to follow up & evaluate optimal progress and manage complications if any.

Dr. Jha discussed 4 interesting yet complicated cases as well where osteosynthesis has been achieved by ilizarov method which provoked further interest among young surgeons.

Felicitation to hon'ble guests and veteran faculties was done. The podium was blessed with the presence veteran Prof. Dr. Tapas Chakraborty (Ex. HOD) who heavily appreciated Dr. Jha's dedication through the years mastering the art of Ilizarov and his struggles of early years of persuasion of the same.

Dr. Jha concluded the ceremony inviting young surgeons to learn the art of Ilizarov. He thanked heartily the organisers, his colleagues, keen students, implant supplier, audio visual aid providers & HCWs of all capacities attached to the department.

He specifically acknowledged Dr. Anirban's efforts & organising capabilities who put every possible effort to make this event a grand success despite all his physical ailments and agonies.

Authors note :

I am not including references that I have used while writing this article trying not to lengthen it further. While writing this I was recollecting the very fact we were doubtful initially whether such a programme could be successfully executed in our set-up, but finally we did it... All glory to the Department & revered Monks attached to the Institute who encourage constantly to achieve seemingly unachievable tasks. On successful completion of the daylong workshop Dr. Bhattacharya's inner feelings were probably like this :

"That I'd ever write a poem... wasn't really God's purpose

But I've written one... it's a revolution, I suppose."

(Adopted & translated from a famous poem of Buddhadeb Basu)



Case Report

Primary Angiosarcoma of The Breast : A Case Report

Sougata Bhattacharjee[1], Soumit Dey[2], Pranamita Ray[3], Chhanda Datta[4]

Abstract :

Primary angiosarcoma of the breast is an extremely rare malignant tumour originating from the breast's blood vessel cells, accounting for less than 0.05% of breast vascular tumours. This aggressive tumour exhibits rapid local recurrence and distant metastasis. Here we present a case report of a 45-year-old female with a rapidly progressing, well-defined breast mass accompanied by skin ulceration. Ultrasound evaluation assigned a BIRADS category of 4A, indicating a suspicious finding for malignancy. Histopathological examination following radical mastectomy confirmed the diagnosis of primary angiosarcoma. Early diagnosis and prompt treatment are crucial for improving outcomes in this rare breast tumor.

Keywords :

Primary angiosarcoma, breast, pathology, diagnosis.

Introduction :

Angiosarcomas originating from the breast are an extremely rare type of malignant tumour, accounting for less than 0.05%[1] of all vascular tumours arising in the breast's connective tissue. These tumours exhibit a high degree of malignancy and display an aggressive growth pattern[2], resulting in rapid local recurrence and the development of metastases in distant organs. The primary method of diagnosing angiosarcomas involves the histological examination of surgically extracted samples. Treatment typically involves the surgical removal of the affected breast by mastectomy. We present a detailed analysis of the epidemiological, diagnostic, and therapeutic aspects associated with this particular disease, combining a case report and an extensive review of the existing literature.

Case report :

A 45 year old female patient presented with a palpable, well-circumscribed, and indolent breast lump measuring approximately 12 cm in its greatest dimension,with a 4 month history of rapid progression.The lump was accompanied by cutaneous ulceration, suggesting an advanced stage of disease. Notably, the patient did not exhibit any axillary lymphadenopathy. Ultrasonography examination assigned a Breast Imaging Reporting and Data System (BIRADS) category of 4A to the lesion, indicating suspicious for malignancy requiring further diagnostic workup. Fine needle aspiration cytology (FNAC) of the lesion produced an inconclusive haemorrhagic aspirate. Subsequent Tru-Cut biopsy of the lesion yielded necrotic tissue fragments, with no viable cells, so it could not provide any categorical opinion.

Given the clinical presentation and diagnostic findings, the patient underwent a radical mastectomy without any specific tissue diagnosis. This aggressive surgical intervention aimed to achieve optimal disease control by removing the primary tumour and potentially involved

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surrounding tissues. The patient remains disease free on follow up.

Figure 1 demonstrates the skin ulceration and dimpling in the nipple areola complex. These clinical findings can be indicative of an underlying pathological condition, possibly including breast angiosarcoma. Further diagnostic evaluation is necessary to confirm the diagnosis and determine appropriate treatment options.

In Figure 2, the cut surface of the breast with the lesion reveals skin involvement, as evidenced by the presence of a haemorrhagic and necrotic area. The margin of the lesion appears ill-defined, and it is located approximately 1cm away from the deep resection margin. These findings suggest an infiltrative nature of the lesion, further emphasizing the need for proper management and treatment considerations.



Figure 1



Figure 2

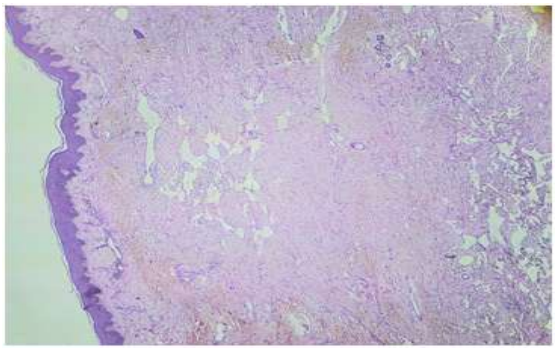


Figure 3 : H&E, X40

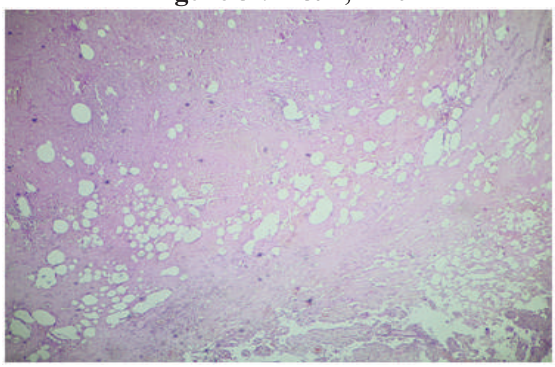


Figure 4 : H&E, X40

Figures 3 and 4 exhibit scanner views that reveal a necrotic area along with some viable lesion. This observation provides a plausible explanation for the presence of necrotic material observed in the tru-cut biopsy. The images suggest a heterogeneous composition of the lesion, with areas of tissue necrosis interspersed with viable tumour tissue.

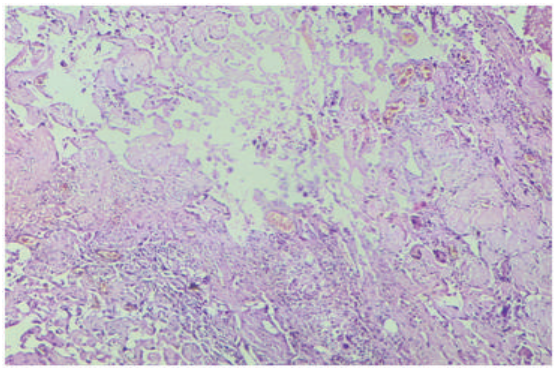


Figure 5 : H&E, X100

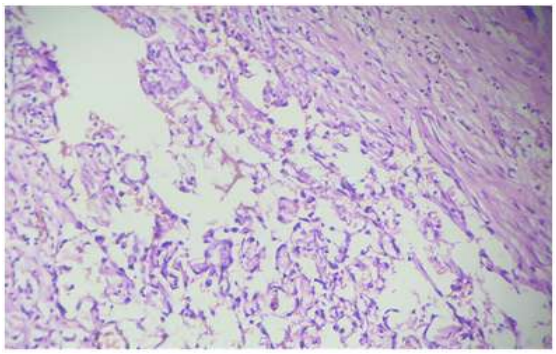


Figure 6 : H&E, X200

Figure 5 demonstrates a low-power view showing inter-communicating spaces. These spaces may indicate the presence of vascular channels. Figure 6 presents a 20X view revealing that the previously observed intercommunicating spaces are lined by flat cells. The presence of flat cells lining these spaces suggests an endothelial origin, indicating a vascular nature of the structures.

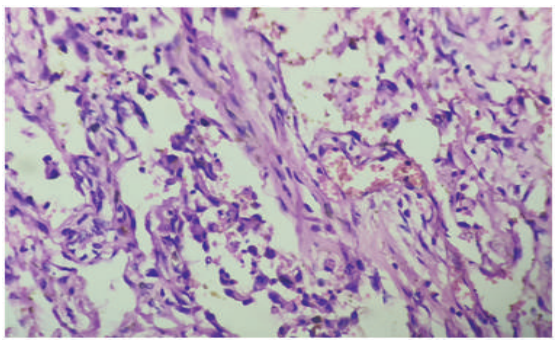


Figure 7 : H&E, X400

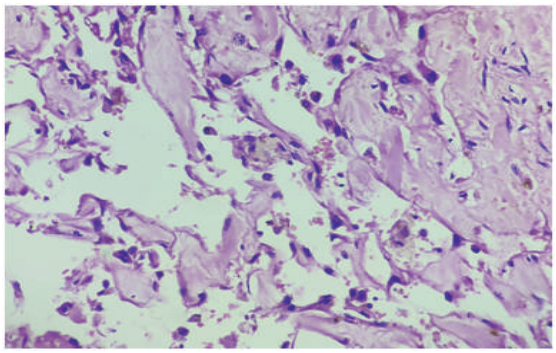


Figure 8 : H&E, X400

Figures 7 and 8 present high-power images revealing that the lining cells of the previously observed spaces are pleomorphic and hyperchromatic. The presence of pleomorphic cells with hyperchromatic nuclei suggests cellular atypia, indicating an abnormal and potentially malignant process. These features raise concerns regarding the possibility of malignancy within the tissue sample.

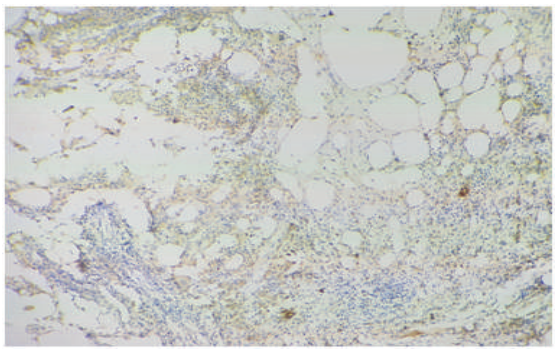


Figure 9 : PAN CK (AE1/AE3)

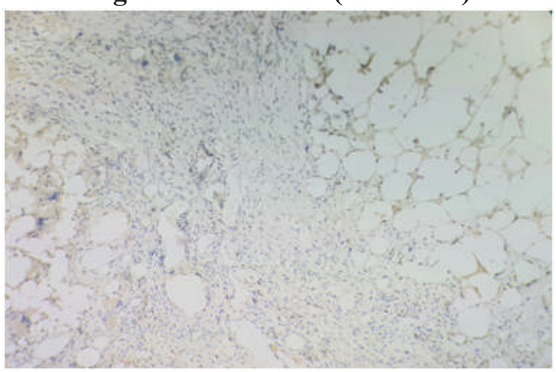


Figure 10 : GATA 3

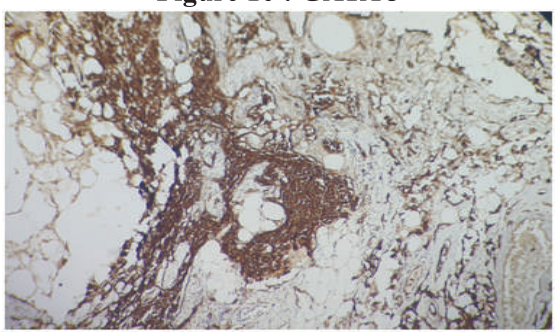


Figure 11 : CD 34

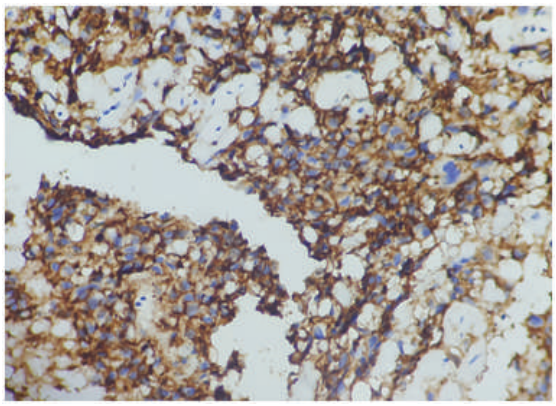


Figure 12 : CD 34

Figure 9 demonstrates the absence of PAN CK staining, indicating that the cells within the examined tissue sample were not of epithelial origin. Similarly, Figure 10 shows the lack of GATA 3 expression, further supporting the non-epithelial nature of the cells. In contrast, Figures 11 and 12 reveal positive staining for CD 34, suggesting the presence of vascular structures or cells with endothelial characteristics. Importantly, there was no history of radiation exposure reported for the patient, so, the diagnosis was consistent with primary angiosarcoma of the breast.

Discussion :

Primary angiosarcoma of the breast is an exceptionally rare malignancy, accounting for only 0.05% of all mammary tumours and 8% of breast sarcomas[1,3]. It predominantly affects women in the age range of 30 to 40 years. Regrettably, the prognosis for primary angiosarcoma is generally unfavourable, with a median survival of approximately 24 months and a five-year recurrence-free survival rate of merely 33%.[4]

Prognostic factors, including histological type, grade, tumor size, and involvement of surgical margins, significantly influence the outcome of primary angiosarcoma.[5] Carcinogenesis of this condition has been associated with various factors such as exposure to vinyl chloride, arsenicas well as chronic irritation induced by foreign bodies and localized trauma.[6]

Accurate differentiation between primary breast angiosarcoma and radiation-induced mammary angiosarcoma is crucial for appropriate management. Clinical presentation of primary angiosarcoma often manifests as a painless nodule exceeding 2 cm in size.[1]

Zellek et al. found that tumour size is correlated with the 10-year recurrence-free survival rate, with tumours larger than 10 cm having a particularly unfavourable prognosis.[7] Primary angiosarcoma of the breast typically presents with purplish, reddish, or angiomatous skin discoloration, while lymph node involvement is rare (0-5% of cases).[8]

Radiological findings are non-specific, but mammography may reveal a well-circumscribed, dense, and sometimes calcified mass, along with focal density asymmetry.[9] Ultrasound shows a heterogeneous mass with areas of necrotic and haemorrhagic changes or a heterogeneous region without a distinct mass.[10] Doppler imaging confirms the tumour's hypervascular nature. MRI demonstrates a heterogeneous low-signal intensity mass in T1-weighted sequences and a high-signal intensity mass in T2-weighted sequences. Haemorrhagic zones or venous lakes may appear as high-signal intensity areas on T1-weighted MRI. The degree of enhancement on MRI depends on the tumour grade.[11]

Donnel et al and Mérino et al have established a correlation between histological grades and prognosis. According to their findings[5], three

grades have been identified. Type I corresponds to a low-grade tumour characterized by the absence of massive necrosis, haemorrhage, or papillary formation. Type II represents an intermediate grade tumour without necrosis or haemorrhage. Type III, on the other hand, represents a high-grade tumour and is associated with the least favourable prognosis. It is important to note that a tumour can exhibit a combination of these three histological types. The determination of the grade plays a crucial role in the differential diagnosis. For grade I tumours, conditions such as sinusoidal haemangioma, angiolipoma, angiomatosis, benign lymphangiothelioma, pseudoangiomatous stromal hyperplasia, and atypical vascular lesions should be considered.[5] In the case of type III tumours, sarcomatoid carcinoma or other high-grade sarcomas, which do not express vascular markers (CD34, CD31), should be included in the differential diagnosis.

In a recent study by Itakura et al.[12], the overexpression of vascular endothelial growth factor (VEGF-A) and VEGFR-1 was demonstrated in various subtypes of angiosarcomas. The standard treatment for angiosarcomas is total mastectomy[13, 14], and the assessment of resection margins plays a critical role in predicting local recurrence. Lymphatic spread is rare, making axillary lymph node dissection unnecessary except in cases of palpable lymph nodes.[6] Adjuvant chemotherapy has shown limited efficacy, but high-grade angiosarcomas have shown improved overall survival and recurrence-free survival with this treatment.[15] Targeted therapy using anti-growth factor antibodies is a promising therapeutic approach. Inhibition of angiogenesis through the exploitation of VEGF-A, VEGF-C, and their VEGF-R1 receptor, which is the primary vascular growth factor, presents an interesting therapeutic target.[16]

Conclusion :

In conclusion, primary breast angiosarcoma is a rare and aggressive tumour that can occur in patients without a history of irradiation. Due to its severe prognosis, early diagnosis and prompt treatment are crucial. However, diagnosing angiosarcoma before surgery is challenging, as clinical, radiological, and histological findings may not definitively indicate its presence. Simple mastectomy is considered the treatment of choice, though in this case radical mastectomy was done, while the role of radiotherapy and chemotherapy in managing this condition is still not fully established. Further research and clinical studies are needed to better understand and optimize the management of primary breast angiosarcoma, ultimately improving patient outcomes.

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Extract From The Gazette of India, NMC Notification August, 2023

National Medical Commission Ethics and Medical Registration Board

Notification

New Delhi, the 2nd August, 2023

No. R-12013/01/2022/Ethics.—In exercise of the powers conferred by section 27(1) b, read with sections 10(b) (f), 16(2), 57(2) zd, zi, zl and zh of the National Medical Commission Act, 2019 (No.30 of 2019), the National Medical Commission hereby makes the following Regulations relating to Professional Conduct of Registered Medical Practitioners namely:-

Preliminary

1. Short Title and Commencement :

(A) These regulations may be called the "National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023.

(B) They shall come into force from the date of their publication in the Official Gazette.

Chapter-1

Professional Conduct of RMPS

2. Duties and responsibilities of the Registered Medical Practitioners : At the time of making an application for registration under the provisions of the NMC Act, it shall be deemed that the RMP has read and agreed to abide by these regulations.

3. Suffix and Modern Medicine :

(A) Every self-employed RMP shall display the unique registration ID assigned to her/him by EMRB in his/her prescription, certificate, and money receipts given to patients. Employed RMP shall get a seal made by the employer for displaying the unique registration number below the RMP's signatures. (L1)

(Guideline for prescription) :

(B) The RMP shall display as suffix to his/her name only NMC recognized and accredited medical degrees/diplomas as provided in the nomenclature of the regulations and listed on the NMC website (List of such Degrees and Diplomas will be on the website and updated regularly). RMPs qualified abroad and seeking registration to practice after clearing FMGE/NEXT must use NMC-approved equivalent Medical prefixes and suffixes to provide clarity to patients and the public at large. (L1)

(C) RMP shall not claim to be a clinical specialist unless he/she has NMC recognized training and qualification in that specific branch of modern medicine (The list of recognized post-graduation and super-specialization degrees/diplomas will be available on the NMC website) (L1 and/or L2).

(D) Every RMP shall practice the system of medicine in which he/she has trained and certified (for this purpose referred to as modern medicine* or allopathic medicine) and shall not associate professionally with any unqualified person to perform any treatment, procedure, or operation. (L2)

(E) RMP shall not employ in connection with his/her professional practice any healthcare professional who is neither registered nor trained

under the relevant Medical Acts in force related to the practice of modern medicine. Provided that having employed any such assistants in the practice, the ultimate responsibility rests on the self-employed RMP or the RMP responsible for administration and recruitment in case of hospital practice.(L2)

* "Modern medicine" or "Allopathy" is a healthcare discipline that involves a scientific understanding of disease processes and uses rational and evidence-based treatment methods. This system of medicine views disease as a biological abnormality in the function or structure of organs or organ systems, with effects on organs and the body as a whole. Animal experiments may be used to understand disease processes and the efficacy of therapeutic measures.

Medical research using blinded studies and statistical analyses informs all aspects of diagnosis, testing, treatment, and disease prevention. Modern medicine has international uniformity in theory and practice. It has found universal acceptance in India and is currently practiced and taught in Government and Private hospitals and medical colleges governed/regulated and accredited by the National Medical Commission, Government of India.

4. Continuing Professional Development Program: A RMP should attend continuing professional development programs regularly each year, totaling at least 30 credit hours every five years. Only recognized medical colleges and health institutions or medical Societies accredited or authorized by EMRB/State Medical Councils can offer trainings and credit hours for this purpose. Credit hours awarded shall be updated online against the Unique Registration Number of RMP on the EMRB-NMC website. Renewal of License to practice should be done every 5 years (from the publication of the Gazette notification), after submitting documentation of CPD credit hours. The license renewal form will allow updates of details like specialization, place of work, address, contact details, or any other detail specified by EMRB/NMC. (CPD guidelines)(L2)

5. RMPs will be licensed to practice in the states after payment of requisite fee in States and their names will appear on state medical register.(L2)

6. Right to remuneration of RMP : Consultation fees should be made known to the patient before examination or treatment of the patient. A reasonable estimation of the cost of surgery or treatment should be provided to the patient to enable an informed decision. RMP can refuse to treat or to continue to treat a patient if the fees, as indicated, are not paid. At the same time this does not apply to doctors in government service or emergencies but the doctor must ensure that the patient is not abandoned. (L1)

7. Prohibiting Soliciting of Patients : RMP shall not solicit patients directly or indirectly or as a part of the group of RMPs, or institutions or organizations or hospitals or nursing homes, or corporate hospitals established, owned, controlled, or maintained by the appropriate government, local authority, trust, whether private or public, corporation, co-operative society, organization or any other entity or person. (L2)

8. Prescribing Generic Medicines : Every RMP should prescribe drugs using generic names written legibly and prescribe drugs rationally, avoiding unnecessary medications and irrational fixed-dose combination tablets. (L1 and/or L2) (Generic Drugs and Prescription guidelines)

9. Prohibition of Fee Splitting/Commissions: A RMP shall not directly or indirectly participate in any act of division, transfer, assignment, subordination, rebating, splitting, or refunding of any fee for diagnostic, scanning, medical, surgical, or other treatment. These provisions shall apply with equal force to the referring, recommending, or procuring by a RMP of any patient, specimen, or material for diagnostic purposes or other studies/work. However, nothing in this section shall prohibit payment of salaries by a qualified RMP to another duly qualified person rendering medical care under his/her supervision. RMP shall not use online forums or agents for procuring patients. (L3)

10. Prohibition of endorsement of a product or person :

A. RMP individually or as part of an organization/association/society etc. shall not give to any person or to any companies or to any products or to software/platforms, whether for compensation or otherwise, any approval, recommendation, endorsement, certificate, report, or statement concerning any drug brand, medicine, nostrum remedy, surgical, or therapeutic article, apparatus or appliance or any commercial product or article with respect of any property, quality or use thereof or any test, demonstration or trial thereof, for use in connection with his name, signature, or photograph in any form or manner of advertising through any mode nor shall he boast of cases, operations, cures or remedies or permit the publication of report thereof through any mode. (L3)

B. A RMP shall not issue certificates of proficiency in modern medicine to unqualified, unskilled, or non-medical persons. This does not restrict the proper training and instruction of bonafide students, midwives, dispensers, surgical attendants, or skilled mechanical and technical assistants & therapy assistants under the personal supervision of RMPs. (L2). Every certificate must contain the details regarding experience, skills and competency obtained, duration of the training, and kind of work done during training. The onus of the veracity of the certificates lies with the RMP. (L2)

11. Advertisement :

A. RMP is permitted to make a formal announcement in any media (print, electronic or social) within 3 months regarding the following: (1) On starting practice (2) On change of type of practice (3) On changing address (4) On temporary absence from duty (5) On resumption of practice (6) On succeeding to another practice (7) Public declaration of charges. (L2)

B. RMP or any other person including corporate hospitals, running a maternity home, nursing home, private hospital, rehabilitation center, or any type of medical training institution, etc. may place announcements in the print, electronic and social media, but these should not contain anything more than the name of the institution, type of patients treated or admitted, kind of doctors and staff training and other facilities offered and the fees. (Guidelines on social media conduct). (L1 and/or L2)

C. RMP is allowed to do public education through media without soliciting patients for himself or the institution. (L2)

12. Responsibility of RMP regarding the sale of drugs :

A. RMP shall not run an open shop to sell medicines prescribed by RMPs other than himself or for the sale of medical or surgical appliances. They are allowed to sell medication only to his/ her own patients. (L2)

B. RMP can prescribe or supply drugs, remedies, or appliances as long as there is no exploitation of the patients. Drugs prescribed by RMP or bought from the pharmacy for a patient should explicitly state the generic name of the drug. (L2)

C. RMP shall not administer, dispense or prescribe secret remedial agents of which he does not know the composition or action in the body. The manufacture or promotion or use of these remedies is prohibited. (L3)

13. Responsibility of RMP regarding the Medical Records :

A. Every self-employed RMP shall maintain medical records of patients (inpatients) for 3 years from the date of the last contact with the patient for treatment, in a standard proforma laid down by the NMC. (Guideline) (L2)

B. If any request is made for medical records to RMP responsible for patient records in a hospital or healthcare institution either by the patient / authorized attendant or legal authority involved, the same may be duly acknowledged and documents shall be supplied within 5 working days. (L2)

C. In case of medical emergencies, efforts should be made to make the medical records available at the earliest. (L2)

D. Efforts shall be made to computerize patient's medical records for quick retrieval and security. Within 3 years from the date of publication of these Regulations, the RMP shall ensure fully digitized records, abiding by the provisions of the IT Act, data protection and privacy laws, or any other applicable laws, rules, and regulation notified from time to time for protecting the privacy of the patient. (L1, L2)

E. RMPs are in certain cases bound by law to give or may from time to time be called upon to give certificates, notifications, reports, and other documents of similar character, signed by them in their professional capacity for subsequent use in the courts or administrative or other purposes. Such reports, certificates, or documents should not be untrue, misleading, or improper. A self-employed RMP shall maintain a Register giving full details of such certificates issued by him/her. (L3)

14. RMP shall cooperate in the investigation against incompetent, corrupt, unethical or dishonest conduct of other members of the profession without fear or favour. (L1)

15. The RMP shall not aid or abet torture, nor shall he be a party to either infliction of mental or physical trauma or concealment of torture inflicted by another person or agency in clear violation of human rights. (L3)

16. Practicing active euthanasia shall constitute unethical conduct. However, in some cases, the question of withdrawing life-supporting devices or measures even after brain death shall be decided following the provisions of the Transplantation of Human Organ Act, 1994 and follow prevailing law regarding the issue. (End of Life Guidelines)

17. The RMP should respect the boundaries of the doctor-patient relationship and not exploit

the patient for personal, social, and business reasons (L2) and in particular, avoid sexual boundary violations. (L4)

18. RMP shall not refuse on religious grounds alone to assist in or conduct of sterility, birth control, circumcision, and medical termination of pregnancy when there is a medical indication. (L3)

19. Informed Consent :

A. Before performing any clinical procedure, diagnostic or therapeutic, or operation, the RMP should obtain the signed documented informed consent of the patient. In case the patient is unable to give consent, the consent of the legal guardian or family member must be taken. The name of the operating surgeon must be mentioned in the medical records. In an operation that may result in sterility, the consent of both husband and wife is required. In case of an emergency, the doctor should try to obtain consent, but if this is not possible, he must act in the best interest of the patient. The medical records should describe the basis of decisions taken in an emergency No act of in-vitro fertilization or artificial insemination shall be undertaken without the informed written consent of the female patient and her spouse as well as the donor. (Consent Guidelines) (L4)

B. RMP shall not publish photographs or case reports of patients without their consent/ permission in any medical or another journal in any manner by which their identity could be revealed. (L1)

C. Clinical drug trials or other research involving patients or volunteers must comply with ICMR guidelines and the New Drugs and Clinical Trials Rules, 2018. Consent taken from any patient or participant for the trial of drug or therapy which is not as per the guidelines shall be construed as misconduct. (Research Guidelines). (L2 and/or L4)

20. Conduct of RMP on Social/Electronic and Print Media shall follow the prescribed guidelines (Social Media Guidelines). (L1)

21. RMP should take due care in practice and exercise reasonable skills as expected, to preserve the life and health of the patient and follow the guidelines (Guidelines on Reasonable Care and Skill). (L4)

Chapter-2

Duties of RMPs Towards Their Patients

22. Keeping appointments :

A. RMP shall endeavor to be prompt in attending to the patients and should keep in time with appointments or visiting/consultation hours. If the RMP is delayed for a valid reason, the patient should be informed. (L1)

B. RMP may also advise referral when necessary to another RMP who is specialized in the treatment of the patient's ailment. (L1)

C. In case of emergency (life and limb saving procedure), RMP shall provide first aid and other services to the patient according to his expertise and the available resources before referral. (L3)

23. **Incapacity:** A Registered Medical Practitioner having any incapacity (induced or otherwise) detrimental to the patient or professional practice, which can affect his decision-making or skill in treating the patient is not permitted to practice his profession for the period of incapacity. Use of Alcohol or other intoxicants or being under inluence during duty which can affect

professional practice will constitute misconduct. (L3 and/or L4)

24. Confidentiality: Every communication between RMP and patients shall be kept confidential. Such communication, whether personal, or related to health and treatment, shall not be revealed unless required by the laws of the state, or if non-disclosure may itself be detrimental to the health of the patient or another human being. (L2 and/or L3)

25. Truth-telling: RMP should neither exaggerate nor minimize the gravity of a patient's condition. He/ She shall ensure that the patient or legally appointed representative has such knowledge of the patient's condition that can assist in making decisions that will best serve the interests of the patient. (L1)

26. Patient care: RMP is free to choose whom he will serve, except in case of a life-threatening emergency. Having accepted a case, the RMP should neither neglect the patient nor withdraw from the case without giving adequate notice to the patient and his family. If a change of RMP is needed (for example, the patient needs a procedure done by another RMP), consent should be obtained from the patient himself or the guardian. The RMP who attends to the patient will be fully accountable for his actions and entitled to the appropriate fees. In case of abusive, unruly, and violent patients or relatives, the RMP can document and report the behavior and refuse to treat the patient. Such patients should be referred for further treatment elsewhere. (L2 and/or L3 and/or L4)

27. Referral: Only such Follow up consultation should be planned as required by the patient. Likewise, laboratory investigations ordered for the patient should be justified. An update/ summary of the clinical condition and reasons for referral must be documented and provided at the referral. Specialist referral must be sought to benefit only the patient and duly justified in medical documents. (L2)

28. Signatures: All signatures in the notes, prescriptions, certificates, orders, referral summaries etc, should carry the RMP's name and NMC Registration number. Electronic generation of orders/prescriptions may help automation of this information. (L1and/or L2)

29. Consultation by Telemedicine : Consultation through Telemedicine by the Registered Medical Practitioner shall be permissible following the Telemedicine Practice Guidelines **(Telemedicine Guideline).** (L1 and/or L2)

Chapter-3

Responsibilities of RMP to Each Other

30. Professional Integrity : In consultations, professional rivalry should not be indulged in. All due respect is owed to the RMP in charge of the case, and no derogatory statement or remark be made which would impair the confidence reposed in him by the patient. For this purpose, professional discussions should not take place in the presence of the patient or family or legally appointed representative. The specialist must provide the clinical opinion only to the RMP who referred the patient. Every discussion/ opinion regarding the patient should be kept confidential. If a referral is sought by an RMP, it should be clarified if the specialist will take over the care of the patient or if the patient will remain with the primary RMP. (L1 and/or L2)

31. RMP as Locum : Whenever RMP requests another RMP to attend to his patients during his temporary absence from his practice, professional courtesy requires the acceptance of such

appointment only when the RMP can discharge the additional responsibility along with his /her other duties. The RMP acting under such an appointment should give the utmost consideration to the interests and reputation of the absent RMP and all such patients should be restored to the care of the latter upon his/her return. (L1 and/or L2)

32. Reporting and Inspection : When it becomes the duty of RMP occupying an official position to inspect and report on an illness or injury, he should communicate this to the RMP in attendance to give him the option of being present. The RMP occupying an official position should avoid making any derogatory remarks regarding the diagnosis or the treatment plan adopted. (L1 and/or L2)

Chapter-4

Duties of RMPs Towards the Public and Allied Healthcare Professionals

33. Public Education and Awareness :

A. RMPs, as good citizens, have a responsibility to disseminate scientific advice on public health issues in the public interest without self-promotion. They should particularly co-operate with the authorities in the administration of sanitary/public health laws and regulations. (L1)

B. RMP should enlighten the public concerning quarantine regulations and measures for the prevention of epidemics and communicable diseases. At all times the RMP should notify the constituted public health authorities of every case of notifiable disease under his care, following the laws, rules, and regulations of the health authorities. RMP needs to involve in public education and awareness activities without involving in the advertisement. When an epidemic occurs, RMP provided with all the necessary medical protection should not abandon his duty for fear of contracting the disease himself. (L1 and/or L2)

34. RMP as a team leader, should recognize the importance of teamwork and respect the practice of different paramedical services. (L1)

35. RMPs and their families must not receive any gifts, travel facilities, hospitality, cash or monetary grants, consultancy fee or honorariums, or access to entertainment or recreation from pharmaceutical companies or their representatives, commercial healthcare establishments, medical device companies, or corporate hospitals under any pretext. However, this does not include salaries and benefits that RMPs may receive as employees of these organizations. Also, RMPs should not be involved in any third-party educational activity like CPD, seminar, workshop, symposia, conference, etc., which involves direct or indirect sponsorships from pharmaceutical companies or the allied health sector. RMP should be aware of the conflict-of-interest situations that may arise. The nature of these relationships should be in the public domain such as clinical drug trials and should not be in contravention of any law, rule, or regulation in force. RMP himself or as part of any society, organization, association, trust, etc. make regarding the relationship with the pharmaceutical and allied health sector industry clear and transparent open to scrutiny. (L3)

36. Power to Draft Guidelines : EMRB will draft the guidelines/codes etc on Generic Drugs and Prescription, CPD Guidelines and Accreditation of Organizations, Telemedicine Guidelines, Code of Ethics, Guidelines on Penalties for Misconduct including the Monetary Penalty, Advertisement Guidelines, End of Life

Guidelines, Consent in Medical Practice, Guidelines on Research by RMPs, Guidelines on Social Media Conduct of RMPs, Guidelines on Reasonable care and skill and Guidelines on Interaction with Pharmaceuticals, as and when required and will amend from time to time.

Chapter-5

Professional Misconduct

37. Professional Misconduct : Any violation of these Regulations, or other applicable Acts related to medical practice which are in force, shall constitute professional misconduct. By issuing these Regulations, the EMRB, NMC, and the State Medical Councils are in no way precluded from considering and dealing with any other form of professional misconduct by registered medical practitioners which do not fall under any of the categories mentioned in the regulations or guidelines or codes appended. RMPs bound by these Regulations will not engage in any activities which violate these regulations and should not enter any employment or other contract that engages in activities in violation of any of these regulations. Conviction of RMP in cases of a cognizable offence involving moral turpitude may result in the suspension of license to practice.

38. Procedure for a complaint of professional misconduct :

A. The aggrieved person will file the complaint to the State Medical council through the website portal/offline, ordinarily within 2 years from the cause of action. (The complaint will be lodged in the SMC where RMP is located at the time of cause of action, both in teleconsultation or in person consultation)

B. Where the aggrieved person is unable to make a complaint on account of physical or mental incapacity, a complaint may be filed by —

a. a family member or relative or friend; or

b. the guardian or authority under whose care treatment was received

c. the legal heir or guardian in case of death of the patient

d. The NMC/EMRB/State Medical Council can initiate a suo-moto case against any RMP taking cognizance of gross misconduct. The suo-moto complaint will be taken up if a simple majority of the NMC/EMRB/State Medical Council members agree to proceed against the RMP.

39. Manner of Inquiry into the complaint :

A. At the time of filing the complaint, the complainant shall submit to the EMRB or State Medical Council five copies for offline applications (till the whole process is made online) of the complaint along with supporting documents and the names and addresses of the witnesses.

B. On receipt of the complaint, the SMC/EMRB/NMC shall send one of the copies received to the respondent within 15 working days. For online complaints, the State Medical Council/EMRB/NMC will send an e-copy and/or physical copy of the complaint to the respondent.

C. The respondent shall file his reply to the complaint along with his list of documents, and names and addresses of witnesses, within a period not exceeding 15 working days from the date of receipt of the documented complaint.

D. The state medical council or EMRB/NMC

shall conduct an inquiry into the complaint following the principles of natural justice.

E. On receipt of the complaint, the State Medical Council shall refer the case for review to the designated committee, with assistance from a panel of experts, if required, specifically formed for this purpose in the stipulated time.

F. The /State Medical Councilor EMRB/NMC shall have the right to terminate the inquiry proceedings or to give an ex-parte decision on the complaint if the complainant or respondent fails, without sufficient cause, to present herself or himself for two consecutive hearings or three hearings in total convened by the /SMC or EMRB/NMC. In such situations, the termination or ex-parte order may not be passed without giving a notice of fifteen days in advance to the party concerned.

G. The parties shall not be allowed to bring in any lawyer to represent them in their case at any stage of the proceedings before the state medical council or EMRB/NMC.

H. In conducting the inquiry, a quorum shall be ensured.

I. No new documents or certificates or evidence or witness will be entertained from either of the parties once the proceedings are initiated (meaning -after the parties have been called for a hearing) unless its admission is cleared by the majority of the members. The complaint cannot be withdrawn after it is admitted by the SMC or EMRB/NMC.

J. The State Medical Council or EMRB/NMC may either of its motion or on an application made by either of the parties have the power to change the subject matter experts, if appointed, by providing a valid reason.

40. Disposal of the Complaints : The State Medical Council or EMRB/NMC after giving the parties concerned an opportunity of being heard, may make any of the following recommendations:

1) Dismiss the complaint

2) Censure/Warn/Reprimand the RMP

3) Recommend counseling to the RMP

4) An alternative penalty can be considered

(Guidelines for alternative penalties can be given by EMRB as and when required)

5) May restrain the RMP from performing the clinical procedure(s) or examination as deemed fit. Holding Suspension i.e. restraining RMP from practice until the case is decided- only with full consensus (Restrain will only be in subject matter of dispute).

6) Suspend the RMP from practice for a temporary period as it may deem fit by removing the name of the RMP temporarily from the National Medical Register.

7) Award monetary penalty as it deems fit as per Section 30 of the NMC Act, 2019 can be given by SMC/EMRB only as and when required and will go to SMC/EMRB/NMC account.

8) SMC/EMRB/NMC can charge monetary penalty upto 10 times of the license fee in case it is found during misconduct complaint case that the RMP has not taken license to practice in the state. (L1 and/or L2)

9) May direct the RMP to undertake specific training courses related to the misconduct/some certificate course/ethics sensitization etc.

10) Permanent removal from NMR under exceptional circumstances by SMC must be ratified by EMRB.

11) Any suspension of RMP will automatically restore at completion of suspension period.

41. Prohibition of review of the order : SMC or EMRB/NMC will not have the power to review its order, and the order will be executed only after the expiry of the period of appeal.

42. Power of the SMC/EMRBNMC : The SMC and EMRB/NMC shall have the same powers as are vested in a civil court under the Code of Civil Procedure, 1908 while trying a complaint against an RMP in respect of the following matters, namely: —

1) The summoning and enforcing the attendance of any defendant or witness and examining the witness on oath.

2) Requiring the discovery and production of any document or other material object as evidence.

3) Receiving evidence on affidavits.

4) The requisitioning of the report of the concerned analysis or test from the appropriate laboratory or any other relevant source.

5) Issuing of commissions for the examination of any witness, or document; and any other matter which may be prescribed by the Central Government.

6) Penalty (L2 to L5) so awarded and confirmed to the RMP by State Medical Council or EMRB/NMC shall be publicized widely on its website and other platforms as they deem fit and communicated to the employer, the nhospital/ healthcare institution of the RMP and respective Medical Associations/Societies/Bodies.

43. Delay in decision : Where the EMRB is informed that a complaint against a RMP has not been decided by a State Medical Council within six months from the date of the complaint, and the EMRB has reason to believe that there is no justified reason for not deciding the complaint within the said prescribed period, then EMRB can direct the SMC to hear the case on day to day basis until the case is duly heard and is closed or may withdraw/transfer the complaint pending with the concerned State Medical Council immediately. The reasons for not deciding the case within the stipulated time shall be mentioned in the order of the SMC. Registrar of the council or person mandated for such job by SMC act will be responsible for making all communications in time to everyone.

44. Appeal :

1) RMP who is aggrieved by the decision of the State Medical Council shall have the right to file an appeal to the Ethics and Medical Registration Board (EMRB) within 60 days from the date of receipt of the order passed by the said State Medical Council: Provided that the Ethics and Medical Registration Board may if it is satisfied that the appellant was prevented by sufficient cause from presenting the appeal within the aforesaid period of 60 days, allow it to be presented within a further period of 60 days.

2) RMP who is aggrieved by the decision of the Ethics and Medical Registration Board may prefer an appeal before the National Medical Commission within 60 days from the date of passing of an order by the EMRB.

3) Order of SMC will become operational after the expiry of the period of appeal (60 days + 60 days). Once in appeal, the order of SMC will be deemed stayed unless decided otherwise by EMRB/NMC.

Guidelines - 1

Generic Medicine and Prescription Guidelines

Preamble :

India's out-of-pocket spending on medications accounts for a major proportion of public spending on health care.

Further, generic medicines are 30 to 80 % cheaper than branded drugs. Hence, prescribing generic medicines may overtly bring down health care cost and improve access to quality care.

Generic Medicines *vs* Generic Names :

Generic Name :

Non-Proprietary or approved name of a drug is also known as the generic name of the drug.

Non-proprietary name is the name accepted by a competent scientific body/ regulatory authority.

Generic drug/medicine :

A generic drug is defined as a "drug product that is comparable to brand/reference listed product in dosage in dosage form, strength, route of administration, quality and performance characteristics, and intended use".

Branded Generic drug :

A branded generic drug is one which has come off patent and is manufactured by drug companies and sold under different companies' brand names. These drugs may be less costly than the branded patent version but costlier than the bulk manufactured generic version of the drug. There is less regulatory control over the prices of these "branded" generic drugs.

Guidance to RMPs :

1. Prescribe drugs with "generic"/"non-proprietary"/"pharmacological" names only.

1.1. In the case of drugs with a narrow therapeutic index, biosimilars, and similar other exceptional cases, this practice can be relaxed.

2. Prescribe drugs rationally and optimally.

2.1. Both overprescribing and under prescribing are to be avoided keeping in mind possible drug interactions.

3. Fixed-dose combinations are to be used judiciously.

3.1. Only approved and rational fixed-dose combinations are to be prescribed.

4. Advocate for hospitals and local pharmacies to stock generic drugs. Prescribe only those generic medicines that are available in the market and accessible to the patient.

5. Avoid prescribing "branded" generic drugs.

6. Encourage patients to purchase drugs from Jan Aushadhi kendras and other generic pharmacy outlets.

7. Educate medical students, patients, and the public regarding the equivalence of generic medicine with their branded counterparts.

8. Should actively participate in programs related to promotion and access to generic medicines.

9. MBBS & PG students will be trained in the value of prescribing generic medicine.

10. Written Prescriptions should be legible and preferably in full CAPITALS to avoid misinterpretation. As far as possible prescriptions should be typed and printed to avoid errors.

Guidelines - 2

The following template may be used for writing prescriptions rationally

Dr.XXXX
Registration no: XXX
Address
Emergency Contact number:

Patient name : **Date :**
Age :
Sex : **Weight :** **Height**
Diagnosis/Provisional Diagnosis
Rx

1. **Inj XXX …mg IV/IM …..hourly for ……days**
2. **Tab/ Cap XXXX ….mg per oral after food three times a day for 3 days**
3. **Syrup/suspension XXXX -— ml per oral after food three times a day for 3 days**
4. **Oint /gel/cream.... Necessary quantity/finger tip to be applied over the affected area …. times a day till improvement.**
5. **Eye Drops XXXX --- drops to be instilled in the right/left eye every 6th hourly for 3 days**

Not to be repeated
To review after 3 days

Signature
(With Seal)
Name
Unique ID/Reg No (NMC)
Qualification

Guideline - 3

NMC Code of Medical Ethics

Preamble :

The National Medical Commission proposes this Code of Medical Ethics, which will serve as the set of commitments of the registered medical practitioner towards patients, society, professional colleagues, and self. NMC Code of Ethics is framed as a self-regulatory set of guidelines reflecting professional as well as social expectations.

The ethical principles that underpin this code of ethics include beneficence, empathy, non-maleficence, respect for patient autonomy and confidentiality, integrity, honesty, and justice. Medical practitioners are expected to uphold these principles for their inherent value in medical practice, and also to foster trust in patients and maintain the dignity of the medical profession.

NMC code of ethics is not intended to establish legal or clinical standards in practice but to provide a set of ethical guidelines according to which the doctor is expected to practice as a medical professional. Ethical guidelines must be differentiated from laws, as ethical standards expected of the medical professional may sometimes exceed legal requirements.

[**Note :** The words 'must', 'shall / should 'and 'may 'are used purposefully in these guidelines and indicate the degree of obligation that the doctor has to follow the guidelines. The word 'must 'indicates a higher level of commitment and obligation required of the doctor, while in the case of 'shall/should 'the level of obligation is less and there could be room for individual judgment.]

Code of Ethics :

The registered medical practitioner

1. Must provide care for the patient with compassion and respect, keeping the best interest of the patient in mind at all times.

2. Should be respectful of the patient's rights and opinion, communicate clearly with the patient, and be honest and transparent in all professional interactions.

3. Must protect patient confidentiality and privacy, and treat every patient equally, without discrimination.

4. Shall ensure one's competency and fitness to practice, and keep up to date with advancements in medical practice. They shall consult with other health professionals, as and when required for the benefit of the patient.

5. Should function in accordance with the laws of the land. When there is a conflict between ethics and law, the doctor is expected to advocate for changes in the law, in the interest of patient care.

6. Shall be responsive to individual and community health needs, and advocate for patients and the wider community they serve in matters of health and welfare.

7. Must not refuse to treat a patient in case of medical emergency, nor discriminate between patients based on gender, race, religion, caste, social, economic or cultural grounds. No patient should be abandoned.

8. Should practice according to his conscience and ethical guidelines, free from external pressures. They should not provide treatments that are not medically indicated, and must not participate in any act of torture.

9. Should promote and model the ethical standards of the profession in the work place, mindful of the moral and professional obligation owed to the patient and society who have reposed trust in the profession.

10. Should not hesitate to report unethical acts, fraud, incompetence, dishonesty, exploitation or misconduct on part of other health care professionals that could result in harm to the patient.

11. Should recognize conflict of interest situations that may arise in practice as they are detrimental to the patient and should avoid or minimize them. In such situations, the patient's interest should take precedent over any other consideration.

12. Should not engage in endorsement or promotion of any drug or medical product for commercial purposes or for personal gains. In sharing findings of research with peers and scientific societies, the practitioner is expected to be neutral and unbiased in the interest of science and patient care.

13. Should protect and minimize risk of patients who participate in medical research, conscious that the dual role as researcher-practitioner would require disclosure to patients and additional regulatory and ethical compliance.

14. Should ensure that professional boundaries of the doctor patient relationship are respected and not violated.

Inclusions :

Declaration of Geneva 2017 called 'The Physician's Pledge'

1. AS A MEMBER OF THE MEDICAL PROFESSION:
2. I SOLEMNLY PLEDGE to dedicate my life to the service of humanity;
3. THE HEALTH AND WELL-BEING OF MY PATIENT will be my first consideration;
4. I WILL RESPECT the autonomy and dignity of my patient;
5. I WILL MAINTAIN the utmost respect for human life;
6. I WILL NOT PERMIT considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing, or any other factor to intervene between my duty and my patient;
7. I WILL RESPECT the secrets that are confided in me, even after the patient has died;
8. I WILL PRACTISE my profession with conscience and dignity and in accordance with good medical practice;
9. I WILL FOSTER the honour and noble traditions of the medical profession;
10. I WILL GIVE to my teachers, colleagues, and students the respect and gratitude that is their due;
11. I WILL SHARE my medical knowledge for the benefit of the patient and the advancement of healthcare;
12. I WILL ATTEND TO my own health, well-being, and abilities in order to provide care of the highest standard;
13. I WILL NOT USE my medical knowledge to violate human rights and civil liberties, even under threat;
14. I MAKE THESE PROMISES solemnly, freely, and upon my honour.

Guideline - 4

Guidelines on Penalties

Preamble :

The document is prepared with the purpose of bringing uniformity across the country in the assessment of liability and award of disciplinary action in case of Professional Misconduct as per these regulations bearing the principle of proportionality in mind.

In both civil and criminal cases, the law enforcement authorities and courts may expect the statutory bodies to examine the case and fix responsibility on RMP as per these regulations.

If misconduct of criminal nature not listed in the regulation is identified by the SMC or EMRB the same may be reported to the relevant lawful authority for further action.

Assessment of attributability and the severity there of

a) During the assessment, the SMC/EMRB/NMC should consider and evaluate other issues that may have contributed to the situation being assessed, including the final outcome of the

patient, beyond the role played by the doctor.

b) The severity of the situation must be decided for each allegation made against the doctor. Harm should be assessed in the context of the following:

1. The fault (s), if any, of the doctor; may or may not have had a direct bearing on the outcome.

2. Other, extraneous factors may have contributed to the outcome. Some examples are listed below:

(i) The disease diagnosed and the associated risk to health/life, according to the prevailing knowledge in the medical literature and as opined by peer professionals, within the inherent limitations/side-effects/complications of medical science.

(ii) The health/immunity/present condition of the patient and the past medical and other histories relevant to the case.

(iii) The reversibility and the probable impact of the line of treatment on the patient's health condition/life.

(iv) The availability, condition, and maintenance of infrastructure; skill, qualifications, and expertise of the doctor/paramedical personnel/ health-care team.

(v) The progress and severity of the disease along with compliance with medical advice.

(vi) The cooperation by the patient and family/caregivers.

(vii) The work pressures in the treatment setting, related to patient flow (e.g., the doctor to patient ratio); or availability of infrastructure/facilities in a particular district/town/or remote area.

(viii) The scope for corrections, in case of error; the reversibility of the outcome.

(ix) The role expected to have been played by the doctor and the scope of duties/obligations imposed as per law. This may be influenced by the Hospital/Clinic/Institution (Public, Private, Charitable, Specialized, General)

c) The quantum of fees/charges at the treatment facility should not influence the judgement of severity.

d) Therefore, the responsibility of the doctor and the extent of liability may be decided after evaluating the alleged harm caused to the patient in the context of the limitations inherent in the patient's clinical features and treatment setting. A balanced decision in this regard must be taken based on consensus by the SMC/EMRB/NMC. This will help in arriving at the level of the disciplinary action, as described in a later section of this document.

Levels of Disciplinary Action as per Breach of Conduct :

When the State Medical Council or EMRB or NMC investigates a case, the disciplinary action awarded needs to be in keeping with the severity of the act of commission of omission. The disciplinary action may be graded at five levels:

Exoneration - This level is appropriate when the Council finds that the doctor is not at fault and has followed all regulations of the National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023. No disciplinary action is warranted and the RMP is exonerated. This decision should be widely published.

Level 1 : Reformation - This may be awarded singly or in conjunction with other levels, in the form of advisory, instruction or warning. Some examples are provided below:

a) General/detailed instructions to the doctor to be more careful (Advisory)

b) Instruction to display qualifications/degree appropriately, especially with regard to specialization/super specialization.

c) Instruction to attend a workshop or academic programs on Ethics, personal/social relations, and/or professional training for medical professionals.

d) Instruction to attend Continuing Professional Development (CPD) programs in a specified field; the number of CME credit points to be specified.

e) Instruction to attend specialized workshop/conference/training (with NMC accreditation).

f) Warning to be careful in future.

Level 2: This penalty may be awarded even when the role of the doctor in causing direct harm was not conclusively proved but the doctor was found to have breached any of the codes listed above.

The maximum action is a suspension of the license to practice for up to one month (30 days).

Level 3 : This penalty may be awarded when the role of the doctor in causing direct harm was conclusively proved and the doctor was found to have breached relevant regulation.

This maximum action is a suspension of the license to practice for a maximum period of three months. Holding suspension can be given in this level as per regulations.

Level 4 : This penalty may be awarded when the role of the doctor in causing direct harm was conclusively proved and the doctor was found to have breached relevant regulations.

The maximum action is a suspension of the license to practice for a period ranging from 3 months to 3 years.

At each of Levels 2, 3, and 4, the extent of action recommended may range from reformation alone to a maximum of suspension for the period indicated at the level, depending on the quantum of responsibility of the RMP for the harm/injury caused.

Level 5 : The last resort is to debar a member permanently from practice (Permanent suspension of license). This penalty may be awarded only after a detailed inquiry, carried out by an Expert Group constituted under the Guidelines, finds that the treating doctor has committed a willful, or intentionally harm/unlawful, prohibited action. This will be taken as a 'unique case' and no precedent will need to be cited.

RMPs who have been exonerated and those who have completed penalties under Level 1 should not be barred from receiving "good standing" certificates if required later.

Guideline - 5

Guidelines on Informed Consent in Clinical Practice

Preamble :

The aim of this guidance document on informed consent in a clinical situation is to promote awareness amongst RMPs of the critical importance and ethical requirement of providing information to patients and taking consent before investigations, treatment, clinical procedures and surgery. It does not apply to consent in medical research situations which should follow the ICMR Guidelines, 2017. This document does not exhaustively list every clinical situation where informed consent is required but applies

to all clinical interventions that require documentation of consent. In the context of patient autonomy and patient rights, informed consent highlights the importance of respecting the patient's right to know about the clinical condition, treatment, and prognosis as well as right to refuse treatment.

Proper documentation of the information shared and the consent procedure is needed to prevent denials, misunderstandings and legal action.

Type of Consent :

Consent can either be implied or explicit.

Implied consent is applicable for clinical examination, including pelvic and PR examinations (The presence of a chaperone is essential when male physicians examine female patients). Explicit informed consent is required for all procedures, treatments, surgery and interventions that have commonly known risks to the patients.

Informed consent can only be taken from adult patients and must be free and voluntary and in a language understood by the patients.

The RMP should be transparent and truthful in disclosing all risks and benefits of the clinical procedure to the patient as well as alternatives to treatments. There should be neither deception nor coercion on the part of the RMP. The information should include all that the patient would need to know to make the decision (Montgomery vs L Health Board)

Consent for illegal procedures would not be deemed valid either legally or ethically.

Type of Information :

The information that must be shared with the patient before consent will depend on the clinical procedure, treatment, and the risks involved. The information shared must be that which any reasonable man would want to know, particularly the most common side effects or complications that can arise.

Surgery :

Consent must be taken for all operative procedures minor or major.

The concept of blanket consent when the patient is admitted or before surgery cannot be defended legally or morally.

The consent must be procedure-specific. Pre-printed procedure-specific informed consent can be made available after prior approval from the SMC or EMRB. However, the responsibility of administering the informed consent is on the primary physician.

The primary surgeon/surgeon's name should be on the consent form in all surgical procedures.

The standard consent form for surgery under anesthesia used by RMPs and hospitals should include specific risks and information related to each case where necessary and the patient's consent documented for the same.

A patient undergoing two separate elective procedures (example: cholecystectomy and appendicectomy) needs to give consent for each Operations.

Similarly, fresh consent must be taken for every new procedure planned for the patient. Consent must be taken separately for surgery and anesthesia because the nature of these procedures as well as the complications is different.

In major surgeries, it is in the interest of the patient to execute an advanced directive nominating a legal representative who can give consent on their behalf if required for further procedures during surgery when the patient is incapacitated.

Since 2013, it has been a legal requirement to document video recording of consent for transplant surgeries.

Emergencies :

In emergencies, consent for treatment should be taken from patients whenever possible or from legal representatives (wherever available) when the patient is unable to give consent. However, the consent process should not interfere with emergency care and response in the best interest of the patients.

When a patient is brought unconscious and without identification, all efforts should be made to identify the next of kin even while emergency treatment is being provided. The doctor can document the absence of surrogate decision-makers and proceed in the best interest of the patient.

Special Situations :

In the case of minors, the parents or guardians must provide consent, although assent may also be needed from children above 8 years of age.

In case of vulnerable groups, it is safer to have a witness during the informed consent procedure, and take the signature of the witness as well.

Informed consent process should never be curtailed or neglected for the reason that the patient is unable to "fully understand".

The elderly, marginalized, illiterate and other vulnerable patients may require additional time and efforts at communication prior to consent.

In the case of extended treatments or complicated cases, consent may need to be an ongoing process.

Patients who are indisposed should be encouraged to assign surrogates who will take decision and give consent on their behalf, should the need arise. This should be documented in the patient's records.

Medical Students and consent :

In examining patients by medical students for teaching/learning purposes, students must be educated about the process and importance of consent.

Medical students should take verbal permission from their patients before examining them and the patient's decision must be respected, including refusal to be examined by the medical student. Patients do not need to give any reason for this refusal and clinical care of the patient must not be adversely affected in such cases.

Sterilization :

In the case of operative procedures which may result in permanent sterilization, it is prudent to take informed consent from both the patient and the spouse unless denial of consent could put the life of patients in danger. RMP should encourage honest disclosure by the patient in their best interests.

Particular care must be taken with consent in infertility treatments like in-vitro fertilisation, embryo transfer or artificial insemination to protect the rights of patients and donors.

Refusal of Consent :

Patients have the right to refuse treatment, and this right should be respected. RMP should communicate all possible outcomes of the refusal to be treated especially in emergency and acute conditions. It is important to document the patient's refusal to be treated and the reasons given for the refusal.

Use of clinical data

Personal data that can reveal the identity of the patient should not be disclosed under any

circumstances. However, for the use of patient's data in academic teaching or clinical case discussions, patient's consent is required. Under no circumstances will the patient's data be posted on social media.

Guideline - 6

Conduct of RMPs on Social Media

Key Principles :

1) The broader principle of medical ethics should guide the use of social media by RMPs

2) RMPs need to distinguish between telemedicine consultation and social media.

3) All written and visual communication should be truthful, respectful, and professional.

Conduct :

1) RMPs can provide information and announcement on social media. However, the information should be factual and can be verified. The information should not be misleading or deceptive, nor should it exploit the patient's vulnerability or lack of knowledge.

2) RMPs should avoid discussing the treatment of patients on public social media or prescribing medicine to patients on the public social media platform. If a patient approaches doctors through public social media, the doctor should guide the patient toward a telemedicine consultation or in-person consultation as the situation warrants.

3) RMPs should not post patients' photographs or scan images (ct/pet scans) on social media. Once an image is posted in social media, it becomes data that is owned by the social media company or the general public.

4) RMPs behavior on social media towards his colleagues should be guided by general principles of medical ethics on professional behaviour.

5) RMPs should not directly or indirectly indulge in the practice of purchasing "likes", "followers", or paying money so that search algorithms lead to their name being listed at the top or registering on software programs (apps) that charge fees for higher ratings or soliciting patients.

6) RMPs should not request or share patients testimonials or recommendations or endorsements or reviews in social media.

7) RMPs should refrain from sharing images of healed/cured patients, or surgery/procedure videos or images displaying impressive results under any circumstances.

8) RMP is allowed to share educative material for the information of the general public. However, communication should be limited to the expertise of the RMP.

9) RMP's webpage should also follow the same guidelines as above.

10) On social media, RMPs should refrain from boundary crossings or violations and conduct themselves with dignity and decorum.

11) Soliciting of patients directly or indirectly through social media is unethical.

Guideline - 7

Form of Certificate Recommended for Leave or Extension or Communication of Leave and For Fitness

Signature of patient

Or thumb impression.....

To be filled in by the applicant in the presence of the government Medical Attendant, or Medical Practitioner.

Identification marks:-

1.....

2.....

I, Dr. ....., after careful

examination of the case certify hereby that.....whose signature is given above is suffering from.....and I consider that a period of absence from duty of.....with effect

from .....is absolutely necessary for the restoration of his health.

I, Dr. ....., after careful examination of the case certify hereby that .....on restoration of health is now fit to join service.

Place..... Signature of Medical attendant

Date..... Registration No. .....

(Medical Council of India/State

Medical Council of.....State)

Note:- The nature and probable duration of the illness should also be specified. This certificate must be accompanied by a brief resume of the case giving the nature of the illness, its symptoms, causes and duration.

Guideline - 8

Format for Medical Record

(See regulation 13)

Name of the patient :

Age :

Sex :

Address :

Occupation :

Date of Ist vist :

Clinical note (summary) of the case :

Prov: Diagnosis :

Investigations advised with reports :

Advice :

Follow up :

Date Observations :

Signature in full.....

Name of Treating Physician

Guideline - 9

List of Certificates, Reports, Notifications etc. Issued by Doctors for The Purposes of Various Acts/administrative Requirements

1) Under the Acts relating to birth, death or disposal of the dead.
2) Under the Acts relating to Lunacy and Mental Deficiency and under the Mental illness Act and the rules made there under.
3) Under the Vaccination Acts and the regulations made there under.
4) Under the Factory Acts and the regulations made there under.
5) Under the Education Acts.
6) Under the public health Acts and the orders made there under.
7) Under the Workmen's Compensation Act and Persons with Disability Act.
8) Under the Acts and orders relating to the notification of infectious diseases.
9) Under the Employees' State Insurance Acts.
10) In connection with sick benefit insurance and friendly societies.
11) Under the merchant shipping Act.
12) For procuring/issuing of passports.
13) For excusing attendance in courts of Justice, in public services, in public offices or in ordinary employment.
14) In connection with Civil and Military matters.
15) In connection with matters under the control of Department of Pensions.
16) In connection with quarantine rules.
17) For procuring driving licence.