INTERNSHIP TRAINING

At
ARTEMIS HOSPITAL, GURGAON

A REPORT ON

Assessment of Insulin Injection Administered in Diabetic Patients: A Clinical Audit

By
Dr. SHEETAL YADAV
PG/20/070

Under the guidance of
Dr. Sumant Swain

Post Graduate Diploma in Hospital and Health Management
2020-2022

International Institute of Health Management Research
New Delhi

This certificate is awarded to

Dr. Sheetal Yadav

in recognition of having successfully completed her
Dissertation in the department of Medical Services

And has successfully completed her Project on

Assessment of Insulin Administration in Diabetic Patients: A Clinical Audit

15th March 2022 to 15th June 2022

At

Artemis Hospitals, Gurugram

She comes across as a committed, sincere & diligent person who has a strong drive & zeal for learning.

We wish him/her all the best for future endeavors.

Flt. Lt. Saras Malik
Chief People Officer
Artemis Hospitals, Gurugram

Mr. Ved Prakash
Controller – Human Resources & Training
Artemis Hospitals, Gurugram

Artemis Medicare Services Ltd. Human Resources

TO WHOMSOEVER IT MAY CONCERN

This is to certify that ***Dr. Sheetal Yadav*** student of PGDM (Hospital and Health Management) from International Institute of Health Management Research, New Delhi has undergone internship training at Artemis Hospital, Gurgaon from 15th March 2022 to 15th June 2022.

The Candidate has successfully carried out the study designated to her during internship training and her approach to the study has been sincere, scientific and analytical.

The Internship is in fulfillment of the course requirements.

I wish her all success in all her future endeavors

27/6/2022

Dr. Sumesh Kumar

Associate Dean, Academic and Student Affairs

IIHMR, New Delhi

Dr. Sumant Swain

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PG/20/070.

Certificate of Approval

The following dissertation titled **"Assessment of Insulin Injection Administered in Diabetic Patients: A Clinical Audit"** at **"Artemis Hospital, Gurgaon"** is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **PGDM (Hospital & Health Management)** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of dissertation.

Name	Signature
Dr. A K Aggarwal	.....
Dr. Nitish Dogra	.....
Dr. Manipadma.	.....
Dr. Sumant Swain	.....

Certificate from Dissertation Advisory Committee

This is to certify that **Dr. Sheetal Yadav,** a graduate student of the **PGDM (Hospital & Health Management)** has worked under our guidance and supervision. She is submitting this dissertation titled "**Assessment of Insulin Injection Administered in Diabetic Patients: A Clinical Audit**" at "Artemis Hospital, Gurgaon" in partial fulfillment of the requirements for the award of the **PGDM (Hospital & Health Management).**

This dissertation has the requisite standard and to the best of our knowledge no part of it has been reproduced from any other dissertation, monograph, report or book.

Institute Mentor -Dr. Sumant Swain
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Designation- Medical Supridendant

Organization-Artemis Hospital, Gurgaon

INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH,

NEW DELHI

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **"Assessment of Insulin Injection Administered in Diabetic Patients: Aclinical Audit"** and submitted by **Dr. Sheetal Yadav** Enrollment No. PG/20/07-under the supervision of Dr. Sumant Swain for award of PGDM (Hospital & Health Management) of the Institute carried out during the period from 2020 to 2022 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.

Sheetal Yadav

Signature
Dr. Sheetal Yadav

FEEDBACK FORM

Name of the Student: Dr. Sheetal Yadav

Dissertation Organization: Artemis Hospital, Sec-51, Gurgaon

Area of Dissertation: Medical Services

Attendance: 98%.

Objectives achieved: Dr. Sheetal has diligently completed all the given work.

Deliverables: Yes. All the tasks assigned were completed.

Strengths: Dr. Sheetal is very hardworking & sincere

Suggestions for Improvement: Needs to build up her confidence in dealing with difficult patients.

Suggestions for Institute (course curriculum, industry interaction, placement, alumni):

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Date: 20/06/2022

Place: Gurgaon

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Summer Internship training is a golden opportunity for learning and self-development. I consider myself fortunate and take this opportunity to express my sincere thanks to **FLT. LT. Saras Malik, Unit Head-HR,** for providing an opportunity to undergo my summer internship at Artemis Hospital, Gurgaon, Haryana.

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I am very grateful to Dr. Sumant Swain, Assistant Professor, IIHMR Delhi, my mentor for guiding and supporting me whenever required. It would not have been possible to complete my study and complete my training successfully without his cooperation.

Dr. Sheetal Yadav
PG/20/070

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Section 1

Organization Introduction

Artemis Health Institute, established in 2007, is a healthcare venture launched by the promoters of the Apollo Tyres Group. Artemis is the first Hospital in Gurgaon to get accredited by Joint Commission International (JCI) (in 2013). It is the first Hospital in Haryana to get NABH accreditation within 3 years of start-up.

According to Greek mythology *Artemis* is the daughter of sky gods Zeus and Leto, and the twin sister of Apollo.

Why Artemis?

Designed as one of the most advanced hospitals in India, Artemis provides a depth of expertise in the spectrum of advanced medical & surgical interventions, comprehensive mix of inpatient and outpatient services. Artemis has put modern technology in the hands of renowned doctors from across the country and abroad to set new standards in healthcare. The medical practices and procedures followed in the hospital are research oriented and benchmarked against the best in the world. Top-notch services, in a warm, open patient centric environment, clubbed with affordability, have made us one of the most revered hospitals in the country.

Artemis Hospitals is the preferred healthcare destination for the employees of various businesses. They get access to quality healthcare with extra personal care, minimal formalities during admission and a variety of corporate offers. In order to ensure better health for employees & their families, Artemis Hospitals actively partners with various corporates by getting empanelled as their favoured healthcare service provider.

The following services are provided to the business houses:

- Executive Health Checks,
- Workplace clinics for counselling,
- Outpatient and hospitalization services,
- Healthcare education and awareness programs,
- First Aid and BLS Training,
- Emergency Services,
- Organizational Healthcare Audit.

Government Empanelment's:

- Assam Government
- Border Security Force
- Central Government Health Scheme (CGHS)
- Delhi Government Employees Health Scheme
- Ex-Servicemen Contributory Health Scheme
- Haryana Government Employees
- Madhya Pradesh Government
- Uttrakhand Govt. (Atal Ayushman Uttrakhand)

Special programs & clinics at Artemis:

- Artemis Preventive Health Check
- Artemis Joint Onco Clinic
- Artemis Artificial Limb Clinic
- Artemis Breast Clinic
- Transplant & Hepatology Clinic
- Pain Clinic
- Safe Spine Surgery Programme
- Stroke Management Centre
- Obesity Clinic

Vision:

To create an Integrated World Class Healthcare System, Fostering, Protecting, Sustaining and Restoring Health through Best in Class Medical Practices and Cutting Edge Technology developed through in depth Research carried out by the World's Best Scientific Minds.

Mission:

- Deliver world class patient care services
- Excel in the delivery of specialized medical care supported by comprehensive research and education
- Be the preferred choice for the world ' s leading medical professionals and scientific minds
- Develop, apply, evaluate and share new technology
- Be an active partner in local community initiatives and contribute to its well-being and development

Core Values:

The corporate value system at Artemis is founded on three pillars – Service, Compassion and Integrity.

- Care for customer
- Respect for Associates
- Excellence through Teamwork

- Always Learning
- Trust Mutually
- Ethical Practices

Leadership Team:

The leadership team at Artemis Hospitals, Gurgaon comprise of the following:

Key Management Personnel

Onkar Kanwar
Chairman

Dr. Devlina Chakravarty
MD

Dr. Manju Aggarwal
Chief Medical Services

Sanjiv Kothari
CFO

Dr. (Col) Manjinder Sandhu
Director – Cardiology

Flt. Lt. Saras Malik
Chief People Officer

Shilpa Budhia
CS & Compliance Officer

Awards:

Awarding Year	Name Of Award	Rewarding Organization
2007	Most Promising Start-up of the year	Express Healthcare magazine
2008	Best IT Implementation	PC Quest magazine for Hospital Information System
2010	CNBC Award Best Medical Value	CNBC Awaaz Travel Awards
2010	Asia Pacific hand hygiene Excellence award	World Health Organization
2013	Best Super Specialty Hospital in Gurgaon	ET NOW & BIG RESEARCH
2016	Certificate of Merit in D.L. Shah Quality Award for the case study "Pathway to Nursing Excellence"	Quality council of India

2016	Patient safety award at International Patient safety conference	Apollo Hospitals
2017	Healthcare Transformation Awards – Mobile Innovations in healthcare	NASSCOM dynamic CIO
2017	Best Hospital in Quality Treatment - State Health Awards	IMA Punjab & AHPI
2018	Best Super Specialty Hospital in Delhi - NCR	Indian Excellence Award 2017
2018	Award for Excellence in Healthcare	The Healthcare Today
2018	FICCI Healthcare Excellence Award 2018 for Service Excellence	FICCI Healthcare
2019	D.L. Shah Quality Silver Award – For the case study End to End Care Delivery	Quality Council of India
2019	One of India's Top 50 Companies with GPMS (Great People Managers Study)	Great Manager Institute in association with Forbes India
2019	Healthcare HR Excellence Award	Recruit
2019	Kayakalp Award for Excellence in promoting cleanliness , hygiene and infection control	Quality Council of India in association with Ministry of Health and Family Welfare, Government Of India
2020	First position in CII National HR Circle Competition (Stream: Innovative Leadership during Crisis)	Confederation of Indian Industry (CII)

HR Vision:

- We are the 'Employer of Choice' for people with professional talent and drive
- We aspire to provide excellent opportunities for professional and personal growth
- We believe in a paradigm shift from 'People Management' to 'Aspiration Management'
- We encourage collaboration, creativity continuous learning and fun based work environment

HR Philosophy:

- Recruit best of the talent
- Develop an environment of trust and respect for each other
- Empower employees with adequate resources
- Recognize and appreciate innovative effort and accomplishments
- Facilitate fun at work place and ensure that employee's efficiency
- Treat all employees uniformly, honestly and with dignity
- Create an environment where teamwork and team goals are encouraged
- Create an open forum to address employee grievances

Artemis Centre of Excellences:

- Artemis Emergency & Trauma Centre
- Artemis Heart Centre
- Artemis Cancer Centre
- Artemis Neurosciences Centre
- Artemis Joint Replacement & Orthopaedics Centre
- Artemis Minimally Invasive & Bariatric Surgery Centre
- Artemis Transplant Centre (Liver, Kidney, Cornea & Bone Marrow Transplant)
- Artemis Women & Child Centre
- Artemis Pulmonology & Critical Care Centre
- Artemis Gastro sciences Centre
- Artemis Cosmetology & Plastic Surgery Centre
- Artemis Pain Medicine & Palliative care

Section-2 Project Report

Abstract:

Diabetes also known as diabetes mellitus, is a chronic health condition. It is a part of a larger global epidemic of non – communicable diseases. 6.6% (i.e. 285 million people) of the world's population is affected by diabetes in the age group of 20-79 years. According to International Diabetic Federation (IDF) report this number is expected to increase to 380 million by 2025. In a report published by IDF in the year 2007 reveals that, India has the largest number of people who are affected by diabetes (40.9 million), followed by China, USA, Russia, & Germany. Diabetes is the 8th leading cause of death. And India is the leading country with more diabetics than any other country, according to International Diabetes Foundation.

Type I diabetes mellitus is among the most common chronic disease in children and adolescents, it accounts for over 90% of all children & adolescent diabetes. Type I diabetic patients require lifelong treatment with insulin therapy.

Type II diabetes mellitus is becoming increasingly common in adolescents, particularly in the peripubertal period. Due to the progressive nature of T2DM, the majority of the subjects will eventually end up requiring insulin therapy to achieve targets for glycemic control once beta cell functions deteriorates & insulin deficiency increases.

Diabetes may lead to serious complication & even life threating complications such as cardiovascular disease, neuropathy, retinopathy, nephropathy, Alzheimer, depression etc. WHO has taken an initiative to support and stimulate the adoption of effective measures for the surveillance, prevention and control of diabetes and its complication, especially in low & middle income countries. WHO has also released a global report on diabetes which provides an overview of the disease burden, interventions to prevent and manage diabetes, recommendations for government, individuals, and the society. WHO has also released a module on diagnosis and management of type 2 diabetes. To create awareness about diabetes **14th November** is celebrated as **"World Diabetes Day"**

The objective of conducting a clinical audit was to evaluate the time difference between the drug/insulin administration and the food intake in diabetic patients who are receiving Novarapid Insulin. The aim of the audit was to introduce the new insulin Fiasp an Ultra – rapid insulin which is a better alternative to Novarapid and improving the treatment of patients on insulin therapy & providing better patient care to insulin dependent patients.

The participants received the fast acting insulin (Novarapid) at the treating physician's discretion as part of the usual clinical practice.

Introduction:

Clinical Audit is a quality improvement process that seeks to improve patients care and outcomes through systematic review of care against explicit criteria & implementation of change.

Aspects of the structure, process & outcome of care are selected and systematically evaluated against explicit criteria. Where indicated changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in healthcare delivery.

The aim of the clinical audit is to measure the gap between ideal practice (determined from evidence & guidelines) and actual practice. The clinical audit process comprises of 8 steps cycle:

1. Select audit topic
2. Defining aims and objectives
3. Selecting standards
4. Methodology: type of study, sampling, source of data
5. Data collection and data analysis
6. Making improvements
7. Sustaining improvements
8. Re-audit, if required

Diabetes also known as diabetes mellitus, is a chronic health condition that affects how the body uses blood sugar (glucose/food) and turns it into energy. It is a part of a larger global epidemic of non – communicable diseases. 6.6% (i.e. 285 million people) of the world's population is affected by diabetes in the age group of 20-79 years. According to International Diabetic Federation (IDF) report this number is expected to increase to 380 million by 2025. In a report published by IDF in the year 2007 reveals that, India has the largest number of people who are affected by diabetes (40.9 million), followed by China, USA, Russia, & Germany.

The burden of diabetes is high & increasing globally, according to WHO reports more than 420 million people worldwide live with diabetes. And in developing countries like India, mainly fueled by the increasing prevalence of overweight/obesity and unhealthy lifestyles. It was reported in 2019 that an estimate of 77 million individuals in India are diabetic, & which is expected to rise to over 134 million by 2045. Approximately 57% of these individuals remains undiagnosed. Diabetes is a major cause for blindness, amputation, kidney failure and cardiovascular diseases & can also result into multiorgan complications. These complications are a significant cause for increased morbidity and mortality among individuals with diabetes.

India contributes approx. 15% to the global diabetes burden & contributes 1% of the world's research on diabetes. Reported projections have shown that this number will increase upto 70 million by 2025. India with a population of 1.2 billion leads the world with earing the dubious distinction of being called as **"Diabetes Capital of the World"**. It has been documented in the papers that approx. 5-10% of the nation's health budget is allocated for the prevention and treatment of diabetes.

Impaired Glucose Tolerance is another mounting health problem in India. Around 35% of the population that suffers from IGT tend to go on to develop type – 2 diabetes. The prevalence

of IGT is more in urban areas - 8.7% & 7.9% in rural areas. It has been noticed that with every diagnosed case of diabetes there is at least one undiagnosed case of glucose tolerance. Therefore, the actual population at risk is much greater than current estimates.

WHO has taken an initiative to support and stimulate the adoption of effective measures for the surveillance, prevention and control of diabetes and its complication, especially in low & middle income countries.

For this WHO has taken a few steps, such as-

- Released scientific guidelines for the prevention of major NCDs including diabetes.
- Developed norms and standards for diabetes diagnosis and care
- Create awareness on global epidemic of diabetes
- Conducts surveillance of diabetes & its risk factors.

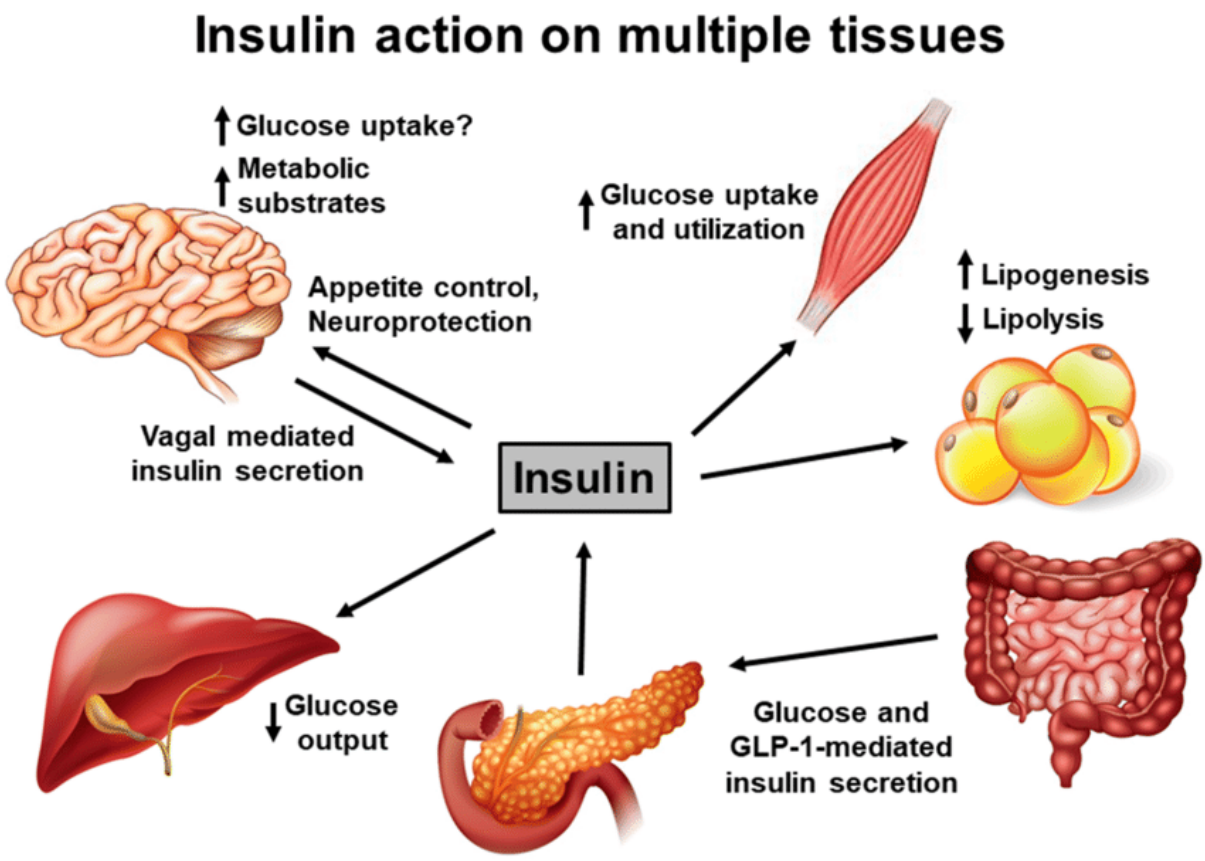
WHO has also released a global report on diabetes which provides an overview of the disease burden, interventions to prevent and manage diabetes, recommendations for government, individuals, and the society. WHO has also released a module on diagnosis and management of type 2 diabetes.

In April 2021, WHO launched the Global Diabetes Compact, an initiative aiming for sustained improvements in diabetes prevention and care. In May 2021, the World Health Assembly agreed a resolution on strengthening prevention and control of diabetes.

Pathophysiology of Diabetes Mellitus

What is Insulin -

- Insulin is a hormone which is produced by the beta cells of the pancreatic islets. It is an essential hormone produced by the pancreas that helps in controlling the glucose level of our bodies.
- Glucose is vital for the health & also an important source of energy for the body cells as it helps to make up the muscles and tissues. It is also considered as a main source of fuel for the brain.
- In Diabetes mellitus is a metabolic disorder in which the body's ability to produce or respond to the hormone insulin is impaired, which leads to hyperglycemia.
- Hyperglycemia is a condition in which there is excess of glucose in the blood stream, which results into dysfunction and damage of multiple organs, including the heart, kidneys, eyes & peripheral nervous system.
- Insulin has multiple action on multiple tissues to regulate the glucose metabolism.

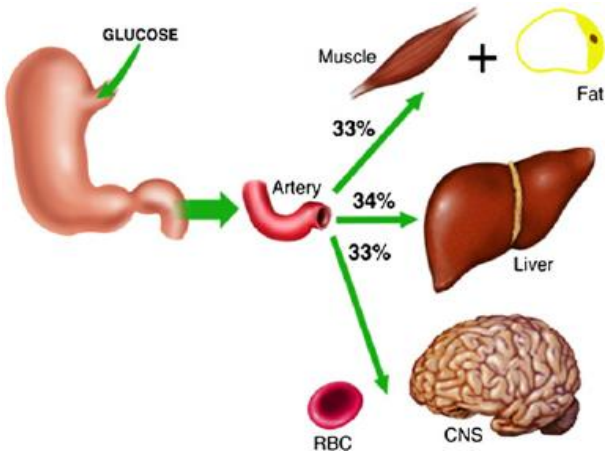


How Insulin Works:

- **The Pancreas secretes insulin into the bloodstream**
- **Then the insulin circulates and enables sugar to enter the body cells**
- **Insulin lowers the amounts of sugar in the bloodstream**
- **As the sugar level drops, so does the secretion of insulin from the pancreas also drops.**
    - **Incase of diabetes, the body either doesn't make enough insulin or the cells can't utilize the insulin it makes as well as it should.**
    - **When there is not enough insulin or the cells stop responding to insulin, it results in accumaulation of sugar into the bloodstream**
    - **which results into hyperglycemia and further leads to serious health cionditions such as, heart disease, neuropathy, nephropathy, etc.**

Role of Glucose:

- Glucose is the energy source for the cells that makes up the muscles and other tissues.
- The two major source of glucose are food and liver.
- Sugar is absorbed into the bloodstream, where it entres the body cells with the help of the insulin.
- Liver stores and makes glucose
- When glucose levels are low, such as when you didn't have meal for a while, the liver breaks down stored glycogen into glucose and helps to keep the glucose levels within the normal range.



Distribution of Glucose

Symptoms of Diabetes:

1. **Polyuria** – It is defined as the need to urinate frequently that helps the body to remove the excess glucose that is filtered from the blood by the kidneys.
2. **Polydipsia** – It is defined as the increased thirst & fluid intake to compensates the loss of fluids that is resulted from the increased urination.
3. **Polyphagia** – It is defined as the increased appetite that compensates for the loss of glucose and fluid from the body due to increased urination.

Types of Diabetes:

1. Type 1 diabetes
2. Type 2 diabetes
3. Monogenic (MODY, Others)
4. Secondary diabetes (infections, drugs & other disorders)
5. Gestational diabetes

Screening guidelines by American Diabetes Association:

1. **Anyone with a BMI higher than 25, regardless of age,** who has additional risk factors, such as high blood pressure, abnormal cholesterol levels, a sedentary lifestyle, a history of polycystic ovary syndrome or heart disease, and who has a close relative with diabetes
2. **Anyone older than age 45** is advised to receive an initial blood sugar screening, and then, if the results are normal, to be screened every three years thereafter
3. **Women who have had gestational diabetes** are advised to be screened for diabetes every three years.
4. **Anyone who has been diagnosed with prediabetes** is advised to be tested every year.

Type 1 Diabetes:

Also known as **Insulin dependent diabetes mellitus.** It is thought to by an autoimmune reaction (condition in which the body cells attack itself by mistake) and stops the pancreas from making/secreting insulin.

Approx. 5 – 10% the population is affected with type I diabetes & is often diagnosed in children, teens and young adults, therefore also known as **Juvenile Diabetes.**

Symptoms of Type I diabetes –

- Extreme thirst (Polydipsia)
- Increased hunger (Polyphagia)
- Dry mouth
- Nausea and vomiting
- Frequent urination (Polyuria)
- Unexplained weight loss
- Fatigue
- Blurry vision
- Heavy breathing
- Frequent infection of skin, urinary tract
- Bedwetting in children

Emergency Signs –

- Shaking and confusion
- Fruity smell breath
- Belly pain
- Rapid breathing

Type II Diabetes:

Also known as **Adult Onset Diabetes/Insulin Non Dependent Diabetes Mellitus.** It is more common than Type I diabetes**,** 90 – 95% of population is affected with type II diabetes. It is characterized by high level of sugar in the blood and either the body doesn't produce enough insulin or the body cells resist the normal effect of the insulin. But the pancreas keeps on producing insulin in response to rising blood glucose level.

Due to body's resistance to insulin, the insulin gets accumulated

finally, the pancreas gets exhausted as it fails to keep up with the insulin demand

and poops out at the end,

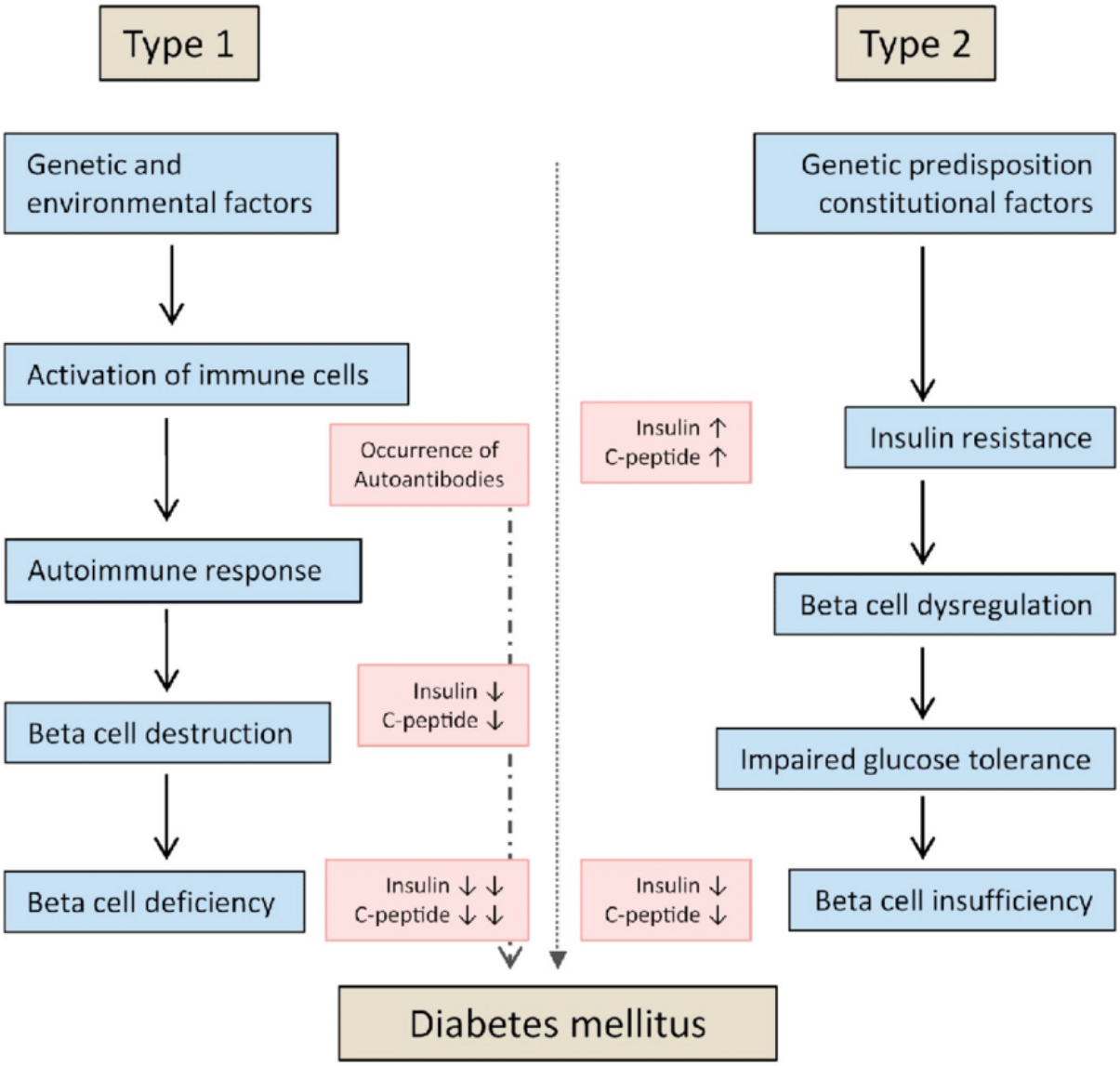
which results in rising the blood glucose level

Symptoms of Type II diabetes –

- Polyuria, polydipsia & polyphagia
- Weight loss
- Increased susceptibility to infection
- Increased hyperglycemia leads to dangerous complication known as **Hyperosmolar syndrome (a life threating condition of dehydration)**
- Glucose lowering medication may lead to hypoglycemia which can be corrected by eating or drinking carbohydrate foods.

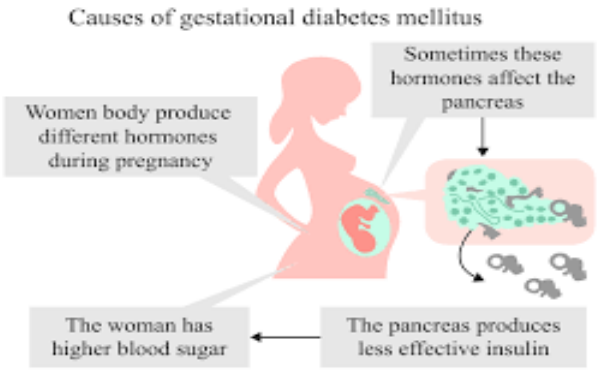
It can also possess some life threating complications also – such as:

- Atherosclerosis
- Retinopathy
- Neuropathy
- Nephropathy
- Foot problems



Gestational Diabetes –

It usually affects the pregnant women & once the baby is born it goes away, but might increase the risk for type II diabetes, later in life. The baby might have obesity as a child or in their teens & are also at risk of developing type II diabetes later in life.



MODY (Maturity – Onset diabetes of the young)

It is defined as a group of several conditions characterized by abnormally high blood sugar levels. This form of diabetes typically has an early age onset, before the age of 30.

Secondary diabetes

It is defined as a diabetic condition that develops after the destruction of the beta- cells in the pancreatic islets and/or the induction of insulin resistance by an acquired disease such as Endocrinopathies. Most common causes are – diseases of the pancreas that destroy the pancreatic beta cells, hormonal syndrome that interfere with insulin secretions, drugs etc.

Risk Factors for Diabetes:

Type I	Type II	Gestational
• **Family history** • **Environmental factors** • **Presence of damaging immune system** • **Geography**	• **Weight** • **Inactivity** • **Family history** • **Race or ethnicity** • **Age** • **Gestational diabetes** • **Polycystic ovary syndrome** • **High blood pressure** • **Abnormal cholesterol & triglyceride levels**	• **Age** • **Family & personal history** • **Weight** • **Race & ethnicity**

Diabetes Mellitus Treatment:

The goal of treating diabetes is to keep the blood sugar levels as close to normal as safely possible. Since diabetes potentially increases risk of cardiovascular & peripheral artery disease, measures to control blood pressure & cholesterol levels are an essential part of the diabetes treatment.

Diabetic patients must take responsibilities for their day to day care. This includes regardless of the type of diabetes, blood sugar monitoring, physical activities, keeping weight and stress under control, oral medication and insulins plays an important role in the treatment line. In this study the line of treatment chosen is insulin.

Insulin therapy -

Insulin was discovered in 1922 by Banting and Best. Commercially available insulin was obtained from pancreases of slaughter animals (Cows & Pigs) and first used in

1923. Insulin is a hormone that aids in glucose homeostasis, metabolism and cell growth. Today insulin is provided in many forms such as insulin mixtures, concentrated insulin, & insulin with alternate route of administration, offering several options to diabetic patients. Patient with type I diabetes, insulin is the line of treatment for survival, whereas, Type II and gestational diabetes also need insulin therapy.

Insulin is not taken orally, or else the stomach enzymes interferes with the insulin action. Therefore, it is often consumed in injectable form through syringe, insulin pen or insulin pump can also be an option. Insulin pump is a device of size of a cell phone which is worn outside the body. A tube connects the reservoir of insulin to a catheter that's inserted under the skin of abdomen. Now there are availability of tubeless insulin pump which are wireless.

Types of Insulin:

There are 4 major types of insulins –

1. **Rapid – acting** - it starts to work in 15 minutes after injecting and reaches peak in about 1 hour and continues to work for 2-4 hours. It helps to correct the high blood glucose level by covering the carbohydrate portion in the food. It is advised to inject it 15-20 minutes before meal than just before meal.
   The amount of insulin needed for correction is calculated by 2 formulae i.e.
   1) Individual's insulin – to – carbohydrate ration (ICR)
   2) Insulin sensitivity factor (ISF)
   3) Example - **Novorapid, Humalog and Apidra**

2. **Regular or short acting -** it starts to work in 30 minutes after injecting & reaches to peak in between 2-3 hours & work for 3-6 hours. It is used by who consumes low carb food to cover the delayed increase blood glucose level. **Example** - Humulin R and Act Rapid
3. **Intermediate – acting –** it starts to work after 2-4 hours after injecting the insulin shot & reaches to peak from 4-12 hours and continues to work for 12-18 hours. **Example** – NPH (Novolin N, Humulin N)

4. **Long – acting –** it takes hours to enter the bloodstream after injecting the shot and lasts upto 24 hours. **Example –** Insulin glargine, Insulin Detemir etc.

In this clinical audit we tried to compare 2 insulins, which are –

1. **Novarapid**
2. **Fiasp**

Novarapid –

It is a rapid – acting insulin, which helps in correcting the high blood glucose by covering the carbohydrate in food. It is taken 15-20 minutes before the meal (a 'pre-bolus') instead of just before meal, because it starts working after 15-20 minutes of injecting the shot. It is indicated in adults with type I & type II diabetes, & in children with type I diabetes.

It is administered subcutaneously & is available in injection with following preparations –

- 10 ml multiple dose vial
- 3 ml single patient use Novolog Flex Pen
- 3 ml single patient use Panfil cartridges for the 3 ml Panfil cartridge device
- 3 ml single patient use Novolog FlexTouch

Fiasp –

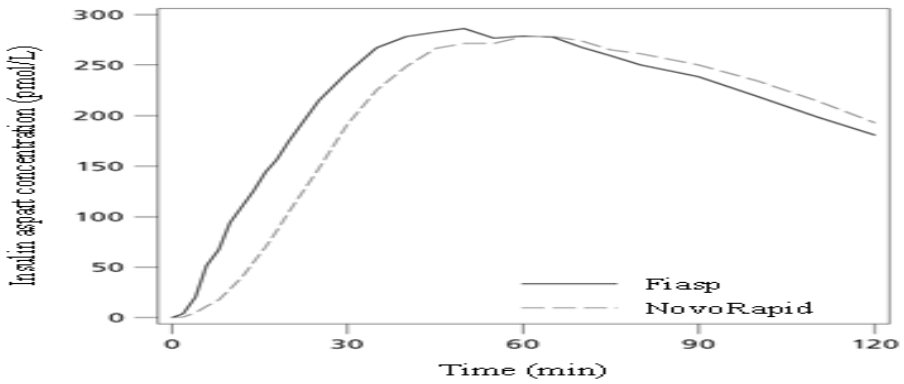
As the name sounds **"FAST**" is an **'Ultra – rapid – acting insulin'.** It is same as Novarapid with addition of 2 ingredients which increases the speed of Fiasp at which it is absorbed in the blood stream i.e. Niacinimide (Vitamin 3) which helps in increasing the initial speed of insulin absorption & Amino acid L – arginine, aids in increased stability of the insulin – makes it work more steadily in its peak.

The objective of developing Fiasp (faster aspart) is that is more closely mimic the physiological mealtime insulin response as compared to other available mealtime insulins.

It is taken immediately before the meal or up to 20 minutes after the meal has started. It is more active in the first hour after the injecting of shot which is useful for carbohydrate food with high glycemic index. It lasts for 4-5 hours and is slightly less active during the final 3-5 hours as compared to Novarapid. As it is fast acting therefore the timing of doses will be different from other insulins & will also require reduction in the basal insulin settings and total daily insulin needs overall.

Insulin	Onset	Peak	Duration
Fiasp	2-15 min	30-60 min	4 hours
Novolog	15 min	45 min	3-5 hours
Humalog	15 min	60 min	3-5 hours
Apidra	15 min	60 min	2-4 hours
Afrezza	4-15 min	35-45 min	1.5-3 hours

Comparison Between Fiasp and other insulins



The graph shows the absorption rate of Fiasp (2X faster) & Novarapid

According to Rachel Head, CDE, Fiasp is beneficial especially for people who have low – fat, high – carb diets. Fiasp can also be helpful in dosing insulin in young children, as it can be done halfway through their meal. Earlier it was not possible, as dosing of insulin would become difficult because parents were not sure about the quantity of the meal.

Side effects of Fiasp –

- Hypoglycemia
- Nasopharyngitis
- Upper respiratory tract infection
- Back pain
- Diarrhea
- Skin problems

Fiasp can be given in both injection and pump form.

Fiasp available as an injection in 100 units/ml are –

1. 10 ml multiple dose vial
2. 3 ml single patient use Fiasp FlexTouch Pen
3. 3 ml single patient use Panfil cartridges for use in a Panfil Cartridge devices.

Literature Review:

- In a Clinical Review by Hyon Kwon, PharmaD, MPH – States that Fiasp was approved in the U.S. for subcutaneous and intravenous administration to improve glycemic control in adults with diabetes mellitus on September 29, 2017. On 21st October, 2019, Fiasp was approved for administration to adults with diabetes mellitus via continuous subcutaneous insulin infusion in the U.S (sNDA 208761-008)

  It also reviewed the efficacy of Fiasp in pediatric patients with T1DM with clinical trials. The trials evaluated the efficacy and safety of meal-time Fiasp and post-meal Fiasp compared to meal-time Novolog in paediatrics patients from 2-7 years of age.

- Fiasp has got the approval in Australia, for use in patients with type I diabetes over the age of 18 years for both injectable and pump form. The FDA, on 6th January gave a green flag for administrating Fiasp in children as young as 2 years to treat diabetic patients Studies says that Fiasp can be used by the pregnant women also but there are not enough clinical trial data to support the recommendation of Fiasp to pregnant.

- Department of Internal Medicine and Diabetology, Medical University of Lodz, Poland – Conducted a clinical trial for assessing the pharmacokinetics parameter of Fiasp. The trial was conducted under the acronym onset, in both T1DM 7 T2DM patients. The results showed comparable or better diabetes control with Fiasp groups as compared to Novarapid groups. Fiasp showed 2 times faster onset of action.

- L Leelarathna et.al. conducted a study to analysis the cost impact of prescribing fast-acting insulin aspart instead of aspart. The study was conducted from the perspective of the UK National Health Services. The Result Showed that the cost impact is neutral for the UK NHS.

- A study states that patients using Fiasp in their insulin pump reported to the family centre that using pump has left them with unexplained high blood glucose after around 48 hours. Whereas patients who inject Fiasp reported to have fewer problems. But if one wants to shift to Fiasp, they must have a prescription from endocrinologist or general physician and support from diabetes educator to transit to new insulin.

- The Food and Drug Administration in September 2016, approved the first artificial pancreas also known as closed-loop insulin delivery, for patients with type I diabetes with age criteria b/w 14 years and above. The second artificial pancreas got approval in December 2019 & after that the systems have been approved even for children older than 2 years old.

Research Aim and Objective:

Aim:

To assess the effective use of Insulin injections & finding better alternatives to improve care of Insulin dependent patients.

Objectives:

- To study timely administration of insulin injections.
- To suggest improvement, the care of patient on insulin.
- To find the better alternative that is not time bounded.

Methodology:

***Study Design**: A* Prospective and Observational study

Study Period: The study would be conducted from 1st April to 15th June 2021.

Study Area: Endocrinology Department, Artemis Hospital, Gurugram, Haryana.

Sample Size: Random sampling according to solvent formula (Screening Population – 200; Sample size – 133)

When it is not possible to study the entire population, a smaller sample is taken using a random sampling technique and solvin's/solvent formula allows a researcher to sample the population with a desired degree of accuracy. Solvin formula is used to calculate the sample size necessary to achieve a certain confidence interval when sampling a population.

Solvent Formula = $n = N/(1+Ne^2)$

For example, for a screening population of 200 samples a margin of error of 0.05 is considered sufficiently accurate, therefore, n = 200/1+200*0.05*0.05 = 133 (The result equals the number of samples required to evaluate the population)

Hence 133 patients will be included in the study to assess the effectiveness of insulin injections

Research Instrument: An Audit tool which will includes the following information about the patient -

- Patients Name
- Unique ID number
- Admitting Consultant
- Prescribing Consultant
- Drug Administered
- Drug Administration Date
- Drug Administration time
- Food intake time etc.

Staff Involved:

- **Endocrinologist**
- **Pharmacist**
- **Nursing staff**
- **F&B**
- **Medical Services**

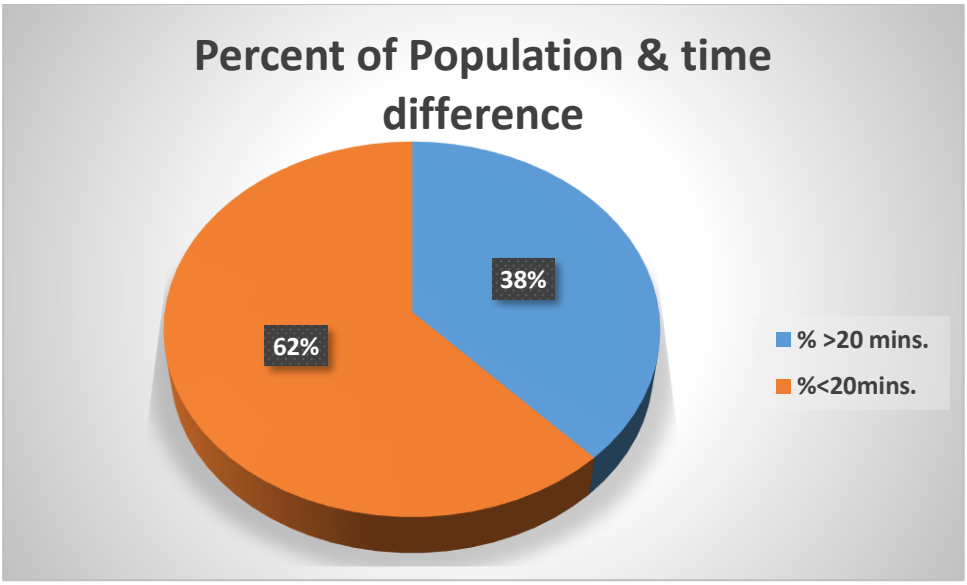
Expected Outcomes: To evaluate the effectiveness two insulin injections which is more effective and results in better patient care and accepted by the patients.

Result

Total of 133 patients who were diabetic were administered the insulin Novarapid & were asked to record the time of insulin administration and the time of meal intake.

Month	Total no. of patients Administered insulin (Novarapid)
April 2022	**100**
May 2022	**33**
Cumulative	**133**

Then, as reported by the patient the data was recorded in the excel & the time difference between the insulin administration and food intake was calculated.



The Pie – Chart depicts the time difference b/w drug administration and food intake

As shown in the diagram –

- Out of total 133 Patients audited, who were administered Novorapid insulin
- 62% patients had their meal within the given time after drug administration (i.e. after 15-20 min. of insulin administration), whereas
- 38% patients exceeded the time limit of 20 minutes after drug administration.

Finding:

- Due to lack of coordination between the nursing, dietetics and kitchen staff there was delay in food servings to patients, therefore resulted in exceeding the time limit beyond 20 minutes.

Corrective and Prevention Action Taken – Introduction of insulin Fiasp (The standard for introduction of Fiasp was set for a limit if 30-40% patient exceeds the time limit of 20 minutes after insulin administration)

- ❖ After the introduction of Fiasp Insulin, timing constraints were taken off and patient care in terms of timely medication administration improved.

Limitations:

- Fiasp is not recommended in pregnancy as there is not enough clinical trial data to support it.
- Age group below 18 were not included in the study.
- Fiasp insulin Pump have reported to have unexplained high blood glucose after around 48 hours (in Australia, but used overseas)
- No direct observation, details were recorded as per the patient's statements.

Conclusion

Diabetes a chronic condition &the disease burden is high and approx. 463 million people globally are living with diabetes from the latest data released by International Diabetes Federation in 2019. The projected number is expected to be doubled by 2030. Type I diabetes makes upto to 5-10% of all the cases whereas Type II diabetes makes 85-90% of all the cases. Diabetes is the 8th leading cause of death. And India is the leading country with more diabetics than any other country, according to International Diabetes Foundation.

According to Indian Heart Association, as the numbers projected, India will be considered to be home for more than 109 million diabetic patients by 2035. The high incidence is attributed to number of factors such as – combination of genetic susceptibility, adoption of high calorie diet, low activity lifestyle by growing middle class. Along with this other factors like obesity/overweight, age, inactivity, stress, family history, race & ethnicity also increase the likelihood for possessing diabetes later in life.

Diabetes may lead to serious complication & even life threating complications such as cardiovascular disease, neuropathy, retinopathy, nephropathy, Alzheimer, depression etc. Therefore, preventive actions should be taken to hault the further progression of the disease. Early diagnosis should be accomplished by blood sugar testing. Type I diabetes cannot be prevented, but necessary action should be taken to help preventing from Type Ii diabetes, prediabetes, gestational diabetes – such as – leading a healthy lifestyle, including healthy food in diet, regular physical activities etc. Other method to stop further progression of the disease is the medication – oral medication, insulin (Injection or Pump).

Insulin injections are more prominently used as patient can now inject it themselves and don't have to visit the doctor for every shot. One such insulin Fiasp is the new evolution in the market, it is the first and only mealtime insulin which enters the bloodstream within 2.5 minutes, 2 times faster than Novarapid. It can be taken immediately before meal or 20 minutes after the start of the meal. Many studies after enough clinical trial data have recommended its usage and is safe to use.

WHO has taken an initiative to support and stimulate the adoption of effective measures for the surveillance, prevention and control of diabetes and its complication, especially in low & middle income countries.

For this WHO has taken a few steps, such as-

- Released scientific guidelines for the prevention of major NCDs including diabetes.
- Developed norms and standards for diabetes diagnosis and care
- Create awareness on global epidemic of diabetes
- Conducts surveillance of diabetes & its risk factors.

WHO has also released a global report on diabetes which provides an overview of the disease burden, interventions to prevent and manage diabetes, recommendations for government, individuals, and the society. WHO has also released a module on diagnosis and management of type 2 diabetes.

In April 2021, WHO launched the Global Diabetes Compact, an initiative aiming for sustained improvements in diabetes prevention and care. In May 2021, the World Health Assembly agreed a resolution on strengthening prevention and control of diabetes.

But one should adopt for healthy lifestyles and healthy habits that can help in preventing the initiation of disease at the first place. In case if the disease has occurred then proper line of treatment and periodic consultation with the doctor is must, from further progression of the disease and preventing oneself from severe and life threating complications.

Recommendation:

- Should not be used in hypoglycemic conditions and patients with hypertension.
- Never share needle or syringes of the insulin vial with other person.
- Do not use the exact same spot for injection every time.
- If a dose is missed – monitor the blood sugar level – than decide if the dose is needed or not – and continue with the regular dose from the next meal.

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