1. INTRODUCTION

The World Health Organization (WHO) and others consider community pharmacists to be ideally positioned to play important roles in facilitating improved patient adherence by, among others, providing patients with comprehensive or cognitive pharmaceutical services (CPS) that include the provision of appropriate health-related information and counselling to promote self-care and the correct use of medicines. [Gerard J. Molloy et al, 2012; WHO, 2003] CPS involves activities both to secure good health and to avoid ill-health in the population. When ill-health is treated, it is necessary to assure quality in the process of using medicines in order to achieve maximum therapeutic benefit and avoid untoward side-effects. This presupposes the acceptance by pharmacists of shared responsibility with other professionals and with patients for the outcome of therapy [FIP, 1997].

1.1 Genesis of Pharmaceutical Care

Pharmaceutical care is a philosophy of practice in which the patient is the primary beneficiary of the pharmacist’s actions. Pharmaceutical care focuses the attitudes, behaviours, commitments, concerns, ethics, functions, knowledge, responsibilities and skills of the pharmacist on the provision of drug therapy with the goal of achieving definite therapeutic outcomes toward patient health and quality of life. [Hepler, CD and Strand, LM., 1990; Commission to Implement Change in Pharmaceutical Education, 1991.]
Clinical pharmacy emerged as a profession in the US during the mid-1960s. The development of clinical pharmacy was partly a result of a change in the pharmacist’s role in the community. Earlier the pharmacist had been an advising, producing and dispensing health care provider in the pharmacy, but during the middle of the 20th century many things changed. The pharmaceutical industry started to manufacture drugs on a large scale, and the need for local production in the pharmacy decreased. In 1951 the prescription only legal status was introduced in the US, limiting the amount of drugs that could be bought over the counter (OTC). There were similar developments in the UK through the Medicines Act 1968, confirming a trend to address patient safety by increasing controls over medicines distribution. The American Pharmaceutical Association (APhA) Code of Ethics from 1922 prohibited the pharmacist from discussing the therapeutic effect and the composition of a prescription with the patient until 1969, when the Code of Ethics was changed. [Jones, RM and Rospond, RM, 2003] These circumstances contributed to making the role of the pharmacist mainly one of dispensing. Many pharmacists wanted to use their knowledge to the best advantage of the individual patient and the population as a whole; the development of clinical pharmacy was a way of doing this.

The concept of pharmaceutical care was developed as a contribution to this discussion. The term pharmaceutical care was first introduced in 1980, but the definition and the concepts which are most widely used today were formulated and presented by Hepler and Strand at the “Pharmacy in the 21st Century Conference” in 1989. [Hepler, CD. 2004; Brodie, DC et al., 1980] This definition was later published in the seminal article “Opportunities and responsibilities in
pharmaceutical care”. [Hepler, CD and Strand, LM, 1990] With this article the concept of pharmaceutical care, as understood worldwide today, was born; but its implementation is far from universal and so remains not as highly developed in reality.

One of the most important roles that pharmacists are currently taking on is one of pharmaceutical care. Pharmaceutical care involves taking direct responsibility for patients and their disease states, medications, and the management of each in order to improve the outcome for each individual patient. Pharmaceutical care has many benefits that include: [website - pharmainfo.net]

- Decreased medication errors
- Increased patient compliance in medication regimen
- Better chronic disease state management
- Strong pharmacist-patient relationship

### 1.2 Pharmaceutical Care Plan

Within the last decades, the role of the pharmacist and of pharmacy practice have moved from that of drug manufacturing and technical dispensing to a more cognitive role with patient orientation [FIP, 1997]. Pharmaceutical care was first defined by Mikeal et al. in 1975 as “the care that a given patient requires and receives which assures safe and rational drug usage” [Mikael, RL et al., 1975]. The concept of pharmaceutical care focuses on the process of ‘using a drug’, bearing in mind that the dispensing of a drug is neither the beginning nor the end of this process. According to the definition of Hepler and Strand [Hepler, CD, 1990],
pharmaceutical care is “the responsible provision of medicine therapy for the purpose of definite outcomes that improve a patient’s quality of life”.

Pharmaceutical care is based on a relationship between the patient and the pharmacist who accepts responsibility for the patient. The concept implies the active participation of the patient in making decisions regarding his/her pharmacotherapy and the interdisciplinary cooperation of healthcare providers, and gives priority to the direct benefit of the patient. Patient expectations and desired quality of life are important factors to ensure the best possible medication outcome, and to possibly prevent recurrence of disease. Pharmaceutical care is an indispensable element of patient centred healthcare and requires a change of traditional professional attitudes, a re-engineering of the pharmacy environment, the use of new technologies, and the acquisition of knowledge as well as skills in the areas of patient assessment, clinical information, communication, adult teaching, and psychosocial aspects of care. [Advit Shah, 2010]

1.3 Need for pharmaceutical care in health care
Pharmaceutical care is a quality assurance system. One of the main reasons for development of this system was an identified need in the society for more effective and safer use of drugs due to more potent drugs and a high incidence of medication errors. [Hepler, CD and Strand, LM, 1990] Pharmaceutical care is a complex system where many health professionals contribute to the total care received by one patient. This makes it difficult to directly measure the influence of the pharmacist in the system. Consequently the research literature on
pharmacist-provided pharmaceutical care is drawn to examining the outcome of defined clinical pharmacy services. The impact of a service can still be difficult to measure and it is often hard to define appropriate measures of the outcomes. This means that the research often has focused on the structure and the process of health care, with an underlying assumption of increased outcomes being achieved by increased quality of the structure or the processes of care. [Tulip, S and Campbell, D, 2001]

1.4 Pharmaceutical Care in Community Pharmacy

Pharmacists individually and as a profession have important roles to play in positively influencing drug policy, drug use and outcomes as well as other aspects of health care. In many instances this will be through collaboration with other health professionals at a community level. [WHO, New Delhi, India, 1988; WHO, Tokyo, Japan, 1993.]

Much of the impetus for pharmaceutical care provision has been driven by academics and only limited published data on the extent to which pharmaceutical care has been adopted and implemented are available. This is particularly true for community pharmacy practices, at a national as well as international level. In 1996, Odedina et al. developed the Behavioural Pharmaceutical Care Scale (BPCS) in the United States [Odedina, FT and Segal, R, 1996]. This scale measures the extent to which pharmaceutical care is provided to patients through assessing a community pharmacist’s recent behavioural activities. Later on, the BPCS scale was modified and used in 2012 by AbuRuz et al. [AbuRuz, S et al, 2012] to evaluate the provision of pharmaceutical care in community pharmacies of
Northern Ireland. Both studies revealed low scores of pharmaceutical care activities at that time. In India, there are few published data available about the provision of pharmaceutical care in community pharmacies. While some aspects of pharmaceutical care were being performed, almost no documentation of efforts was taking place in community pharmacy. Major barriers to the general provision of cognitive services by pharmacists are their incomplete training in this regard, as well as the issue of reimbursement or compensation [Shafie, AA and Hassali MA, 2010].

1.5 Process of Pharmaceutical Care
Pharmaceutical care is based on collaboration between the patient, the practitioner and other health professionals. Pharmaceutical care involves three major functions: [Hepler, CD and Strand, LM, 1990.]

1. Identifying potential and actual drug therapy problems
2. Resolve actual drug therapy problems
3. Prevent potential drug therapy problems

The three functions are performed in order to reach the goal of the pharmaceutical care system, namely achieving definite outcomes that improve or maintain a patient’s quality of life. [Hepler, CD and Strand, LM, 1990; WHO, Developing Pharmacy Practice, 2006.] This requires a logical and structured way of how pharmacists and other health care providers think and act; furthermore a possible means of structuring the deeds in order to perform the three functions is proposed by Cipolle, RJ et al in 2004. [Cipolle, RJ et al, 2004.] This way of
structuring the provision of pharmaceutical care is called the Pharmacist’s Workup of Drug Therapy (PWDT). It has been developed in the US where pharmaceutical care is more developed and has been delivered for a longer time and in a more extensive way, within both primary and secondary care settings, than in the UK. This can be an advantage because the system has been modified and improved based on experience from clinical use.

1.6 Assessment of Pharmaceutical Care

The purpose of the assessment is to decide if the patient’s drug-related needs are being met. If they are not met a potential or actual drug therapy problem exists. A patient’s drug-related needs are described as all the health care needs of the patient related to drug therapy. In order to evaluate if the patient’s drug related needs are met the practitioner has to assess what the patient’s drug related needs are. In the first part of the assessment the practitioner collects relevant patient specific data. This data includes the patient’s demographics, medication experience and relevant clinical information, Table No. 1.1.

Table No. 1.1: Assessment of Patient Related Data

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<thead>
<tr>
<th>Patient Demographic</th>
<th>Medication Experience</th>
<th>Relevant Clinical Information</th>
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<tr>
<td>Name</td>
<td>Drug history</td>
<td>Presenting complaints</td>
</tr>
<tr>
<td>Date of birth/age</td>
<td>Current medical</td>
<td>Relevant laboratory values</td>
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<td>Gender</td>
<td>conditions with</td>
<td>Medical history</td>
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This information and other relevant information provided by the patient are used to evaluate if all the patient’s drug-related needs are being met and to identify potential or actual drug therapy problems. Drug therapy problems often evolve as a result of unmet drug-related needs. A drug therapy problem is defined as “any undesirable event experienced by a patient which involves, or is suspected to involve, drug therapy and that interferes with achieving the desired goals of therapy”. A drug therapy problem consists of an actual undesirable event or the risk of an undesirable event, one or more possible associated drugs and a relationship between the suspected drug(s) and the event. All three aspects of the drug therapy problem must be identified in order to find a solution of the problem. To be able to recognise an undesirable event the practitioner and the patient must know what to expect from the drug therapy (e.g. what kind of effect could be anticipated?) and how these expectations relate to time (e.g. when can effect be anticipated?). [Cipolle, RJ et al, 2004.]

1.7 Stages in Pharmaceutical Care Plan

The care plan is a tool the practitioner uses to resolve and prevent drug therapy problems in order to achieve the goals of therapy. The first thing the practitioner has to do is to determine the goals of therapy; this is done in co-operation with
both other health professionals and the patient. The goal of therapy should be stated on the care plan as a clear statement to the patient, the practitioner and other health professionals. To have a clearly defined and measurable goal of therapy is crucial in evaluating the actual outcomes from the drug therapy. The goal of therapy forms the basis of the care plan and the choice of interventions to resolve/prevent drug therapy problems.

The drug therapy problems should appear in prioritised order on the care plan. The practitioner has to recommend interventions to resolve/prevent the drug therapy problems identified in the assessment. Both goal of therapy, drug therapy problems, recommended interventions to resolve/prevent the drug therapy problems, the follow-up schedule and actual outcomes are documented on the care plan.

1.7.1 Follow-up Evaluation in Pharmaceutical Care

The follow-up evaluation is scheduled according to the timeframe for expected effect and/or adverse effects of the patient’s drug therapy. The purpose of the follow-up evaluation is to determine the patient outcomes and compare the results with the goals of therapy. The practitioner and the patient should also use the follow-up to assess if any new drug therapy problems have evolved since the last meeting. Interventions to resolve or prevent these should be implemented. The follow-up evaluation makes the delivery of pharmaceutical care a continuous and dynamic process, where the changing drug-related needs of the patient guide the care.
1.7.2 Documentation in Pharmaceutical Care

Accurate documentation is important in pharmaceutical care, and the importance will only increase as more pharmacist become prescribers. Documentation is mandatory in pharmaceutical care for legal and ethical reasons, and for quality assurance functions. [Cipolle, RJ et al, 2004; ASHP guidelines on documenting pharmaceutical care in patient medical records, 2003] When the pharmacist assumes responsibility for the patient and patient outcomes from drug therapy he/she agrees to make decisions and recommendations regarding the health of the patient. These decisions and recommendations have to be recorded along with commenced interventions and actual outcomes. Formal documentation is viewed as one of the key concepts that form the basis of pharmaceutical care. [Koda-Kimble, MA et al, 2005] There are various reasons to record the pharmaceutical care delivered. Documentation is important for the continuity of patient care, and is essential in communication with other health professionals. [ASHP guidelines on a standardized method for pharmaceutical care, 1996] A complete documentation simplifies the delivery of care from the patient’s health care team, as all members know what the others are doing, and it makes pharmaceutical care an integrated part of the health care of the patient. The documentation can also be used in research, education and to evaluate the quality of care delivered. American literature underlines the importance of documentation in the prospect of reimbursement of pharmaceutical care services. [ASHP guidelines on a standardized method for pharmaceutical care, 1996] All NHS services are free of charge, however, documentation in pharmaceutical care have economical aspects in the UK as well.
1.7.3 Documentation Requirements

A requirement in the documentation of pharmaceutical care should be that another person than the provider is able to tell what has been done by reviewing the documentation. The reviewer should be able to understand the reason for a recommendation or an intervention, and should also be able evaluate the quality of care given without the need to gather additional data. It is not easy to know what to document, and this is a skill that develops by experience with care planning. It is important that the documentation is complete, but it is just as important not to document unnecessary information. [The Royal Pharmaceutical Society of Great Britain, 2006.]

More detailed lists of what might be necessary to record exist. A pharmacist is not required to record all activities, and the extent of the documentation will vary depending on the situation. A study has shown that clinical pharmacists prioritised to record care issues they consider clinical important or clinical interesting for other pharmacists. Furthermore, situations where a doctor was contacted, especially if the advice given was not accepted, and situations where there was possibility of further developments or problems was considered important to record. The situations mentioned by the pharmacists in the study coincide with situations the RPSGB recommend pharmacists to consider as worth recording. [Gohar, F et al, 2008]

1.7.4 Methods of Documentation

Different systems for documenting of pharmaceutical care have been proposed. A common feature of most of the systems is to divide the record into history,
assessment and plan. [Cipolle, RJ et al, 2004.; Koda-Kimble, MA et al, 2005; Canaday, BR and Yarborough, PC, 1994] The documentation system SOAP (Subjective, objective, assessment and plan) used by doctors is proposed as a possible tool for pharmacist documentation. However, this system is not developed specifically for clinical pharmacists’ use, and a system that takes drug-related problems and not just medical problems into account would be preferable. Use of standardised forms to record patient information is recommended. [Koda-Kimble MA et al, 2005; Canaday, BR and Yarborough, PC, 1994] The PWDT integrates recording as part of the pharmaceutical care process, and documentation of the assessment, the pharmaceutical care plan and the followup evaluation is emphasised. [Cipolle, RJ, 2004] In Scotland a similar documentation system, the Patient Medication Profile (PMP), is used. [Clinical Resource and Audit Group, 1996] The PMP comprises patient details, reason for admission, drug and medical histories, results from investigations, patient’s risk factors affecting medication use, diagnosis, pharmaceutical needs and a pharmaceutical care plan. In the pharmaceutical care plan each identified drug therapy problem is recorded as a pharmaceutical care issue. Desired outcome, action and actual outcome are recorded for each care issue. The pharmaceutical care plan can be evaluated by comparing desired and actual outcomes and it forms a basis for peer review. [Cipolle, RJ et al, 2004]

The composition of these two systems, the PMP and the PWDT, guides the structured and logical process of pharmaceutical care delivery. This increases the usefulness of the information gathered through the systems, both for the
pharmacists and for potential reviewers, and helps the pharmacist avoid omission of important information.

1.7.5 Recording of Pharmaceutical Care Information

In the systems, data is recorded separately from the patients’ medical record, and the pharmacist is often the only one to use the information. Some parts of the information are important to share with other parts of the health care team. This might be done in order to record advice given to patients, to improve communication and to record advice given to other health care professionals. Increasingly it is recognised that pharmacists can, after adequate training, record important issues and problems in patient medical notes shared with other health care professionals. [ASHP guidelines on documenting pharmaceutical care in patient medical records, 2003; The Royal Pharmaceutical Society of Great Britain, 2006.]

1.8 Drug Use Evaluation

“A Drug Use Evaluation (DUE) or Medication Use Evaluation (MUE) program is a planned, criteria-based systematic process for monitoring, evaluating, and continually improving medication use, with the ultimate aim of improving medication-related outcomes for a group of patients or consumers” [Marjorie, A and Shaw Philips, MS, 2002]

DUE is called by different terms namely drug utilization review, drug usage review, drug use review, drug use evaluation, and drug utilization evaluation. It is an important component of health care organizations’ quality improvement
program. The goal of MUE is to provide all patients with the most rational, safe, and effective drug therapy through the assessment and improvement of specific medication use processes. MUE may focus on a specific medication, a class of medications; medications used in the management of a specific disease state or clinical setting, medications related to a clinical event, a specific component of the medication use process, or can be based on specific outcomes [Ninno, MA and Ninno, SD, 2001].

The demand for and hence the cost of health care are increasing in all countries as the improvement and sophistication of health technologies increase. Medicines form a small but significant proportion of total health care costs and one that has been growing consistently as new medicines are marketed. Many governments are focusing their activities on promoting the effective and economic use of resources allocated to health care [Cooke, J, 2007].

Non-communicable diseases are a worldwide problem as shown by their 27% contribution to the global burden of diseases in 1990. This figure is expected to increase to 43% by the year 2020. Non-communicable diseases also have economic consequences for the nation because patients and their families spend money on medical care, the government pays for those attending public health care delivery centres and other organisations such as Medical Aid companies also contribute towards the payment of medical costs. Another financial impact is that employers can lose skilled employees due to disability and morbidity related to non-communicable diseases. [http://www.who.int/chronic_conditions/burden/en/ Accessed December 2013].
An example of a non-communicable disease prominent throughout the world is diabetes mellitus (DM), the control of which is far from optimal [Steyn, K. 2002]. Effective management of DM requires both medicinal and non-medicinal therapy. Whilst patients have no control over the choice of medicinal therapy they receive from their Health Care Providers, DM patients can limit the progression of the disease through lifestyle changes. These individuals therefore need to be educated on how their lifestyles can be altered to reduce the incidence of, for example, microvascular and macrovascular complications which occur due to poorly controlled DM. [Awanish Pandey et al, 2011]

Patient education programmes are effective in increasing patients’ knowledge about a condition, modifying beliefs about medicines, as well as their medication-taking behaviour, and improving health related outcomes. These programmes can take various forms including Focus Group Discussions (FGDs), distribution of written information, Internet-based learning and oral presentations addressing patients as individuals, in groups or the community as a whole. [Abdelmoneim Awad et al, 2011; Lisa M McAndrew et al, 2008]

1.9 Diabetes

1.9.1 Definition

DM is a group of metabolic disorders characterised by hyperglycaemia and abnormalities in carbohydrate, fat and protein metabolism. DM2 accounts for 90-95% of those with DM. Previously, it was referred to as non-insulin dependent diabetes mellitus, type II diabetes or adult-onset diabetes. It encompasses
individuals who have insulin resistance and usually have relative insulin deficiency [American Diabetes Association, 2004; Wells, BG et al, 2003]. At least initially, and often throughout their lifetime, these individuals do not need insulin treatment to survive.

1.9.2 Type 1 Diabetes Mellitus

Type 1 diabetes mellitus is recognised by an absolute deficiency of insulin resulting from immune-mediated destruction of the β-cells of the pancreas. Only 5 to 10% of people with diabetes fall into this category previously known as insulin-dependent diabetes mellitus (IDDM) or juvenile-onset diabetes. It usually presents in early childhood and has a peak incidence around puberty, however it can present at any age.

The autoimmune destruction of the β-cells is related to multiple genetic predispositions and environmental factors that are still poorly defined. The rate of β-cells destruction is quite variable and the patient becomes overly diabetic only when more than 90% of the β-cells have been destroyed [Rang, HP, 2003]. Onset of the disease is in most cases abrupt and may present with ketoacidosis as the first manifestation of the disease. The patient also typically presents with all of the classical symptoms: polydipsia, polyuria, polyphagia, weakness, weight loss and dry skin, which makes it easy to diagnose. The majority of these patients require insulin for survival, even though some patients may briefly return to normoglycaemia. [American Diabetes Association, 2007; Herfindal ET and Gourley DR, 2000.]
1.9.3 Type 2 Diabetes Mellitus

Type 2 diabetes mellitus is the most common type of diabetes. It is responsible to approximately 90 to 95% of all cases. This form of diabetes was previously referred to as non-insulin dependent diabetes (NIDDM) or maturity onset diabetes. The main characteristics of type 2 diabetes are impaired insulin secretion and some degree of insulin resistance of target tissues, primarily the liver and skeletal muscle. Many patients therefore have normal to elevated levels of insulin, due to increased secretion of insulin in an attempt to compensate for the diminished activity of insulin. Despite this blood glucose levels rise due to the insulin resistance. These pathological and functional changes may be present over a long period of time without any clinical symptoms before diabetes is detected. Such patients are at increased risk of developing macrovascular and microvascular complications. [Herfindal, ET and Gourley, DR, 2000; Rang HP et al, 2003; American Diabetes Association, 2007]

Typically type 2 patients are over 40 years of age and most of them are obese, and obesity itself causes some degree of insulin resistance. Weight loss and oral hypoglycaemic drugs may improve insulin resistance. The risk of developing this form of diabetes increases with age, obesity and lack of physical activity. Today there are an increasing number of people in younger age groups with type 2 diabetes due to obesity and sedentary lifestyle. [Diabetes in the UK 2004, 2004]. The International Diabetes Federation (IDF) has stated that up to 80% of type 2 diabetes is preventable by adopting a healthy lifestyle, in terms of nutrition, physical activity and ideal body weight. [IDF]
1.9.4 Prevalence of Diabetes World Wide

Diabetes is a serious condition not only for the individual, but for Society as a whole. It currently affects 246 million people world-wide and this number is expected to increase to 380 million by 2025. Developed countries have a higher prevalence of diabetes than developing countries, but the increase of people with diabetes is projected to increase in both. Developing countries will be hit the hardest by the growing diabetes epidemic. An aging population, a shift towards a more sedentary lifestyle, increasing numbers of overweight and obese people and unhealthy diet are possible factors contributing to this alarming increase of diabetes prevalence. Growing urbanisation is also believed to be a possible contributing factor to the problem. According to the International Diabetes Federation, the five countries with the highest diabetes prevalence in 2007 are Nauru (30.7%), United Arab Emirates (19.5%), Saudi Arabia (16.7%), Bahrain (15.2%) and Kuwait (14.4%). [The International Diabetes Federation, www.idf.org]

1.9.5 Diagnosis

In 1997, the Expert Committee of the American Diabetes Association issued new diagnostic criteria for DM. Subsequently, in 2003, modifications were made regarding the diagnosis of impaired fasting glucose (IFG). [American Diabetes Association, 2004] For non-pregnant individuals of any age, a diagnosis of DM can be made when one of the following is present:

1. Classic signs and symptoms of DM (polyuria, polydypsia, ketonuria and rapid weight loss) combined with a random plasma glucose >11.1 mmol/L.
Random is defined as any time of the day without regard to time since last meal.

2. A fasting plasma glucose (FPG) >7 mmol/L. Fasting is defined as no caloric intake for at least 8 hours.

3. Following a standard oral glucose challenge (75g glucose for an adult or 1.75g/kg for a child), the venous glucose concentration is > 11.1 mmol/L at 2 hours and > 11.1 mmol/L at least one other time during the test (0.5, 1, 1.5 hours); this is the oral glucose tolerance test (OGTT).

The diagnosis must be confirmed on a subsequent day by any one of the aforementioned conditions in the absence of unequivocal hyperglycaemia with acute metabolic complications. Individuals with FPG values or OGTT values that are intermediate between normal and those considered diagnostic are considered to have IFG or impaired glucose tolerance (IGT). These individuals are not given diagnosis of DM because of broad social, psychological and economic implications. The category of FPG values are as follows:

1. A normal FPG is < 5.6 mmol/L
2. An FPG 5.6-6.9 mmol/L is IFG
3. An FPG > 7.0 mmol/L indicates a provisional diagnosis of DM that must be confirmed, as described previously.

The corresponding categories when OGTT is used for diagnosis are as follows:

1. A 2-hour post-load glucose (2-hPG) < 7.8 mmol/L indicates normal glucose tolerance.
2. A 2-hPG > 7.8 mmol/L and < 11.1 mmol/L indicates IGT.
3. A 2-hPG > 11.1 mmol/L indicates a provisional diagnosis of DM, which must be confirmed by a second test.

Many factors can impair glucose tolerance or increase plasma glucose, and these must be excluded before a firm diagnosis of DM is made. For example, an individual who has not fasted for a minimum of 8 hours may have an elevated FPG; one who has fasted too long (> 16 hours) or has ingested insufficient carbohydrates before testing may have an IGT. Patients who are tested for glucose tolerance during, or soon after, an acute illness (e.g. a myocardial infarction) may be misdiagnosed because of the presence of high concentrations of counter-regulatory hormones that increase glucose concentrations; glucose tolerance often turns to normal in these individuals. Pregnancy, many forms of stress, and lack of physical activity can affect glucose tolerance similarly. Many drugs may alter glucose tolerance due to their effects on insulin release and tissue response to insulin, as well as through direct cytotoxic effects on the pancreas. Drugs and other chemicals may also falsely elevate the plasma glucose concentrations through interference with specific analytical methods.

1.9.6 Symptoms
The symptoms of DM2 are usually slower in onset and less severe than in type 1 diabetes mellitus (DM1). Those symptoms typical of type 2 diabetic include:

- polyuria (frequent urination)
- polydipsia (increased thirst and consequent increased fluid intake)
- fatigue
➢ blurred eyesight
➢ slow healing cuts or sores
➢ sexual dysfunction
➢ numbness/tingling in hands and feet
➢ frequent infections
➢ dry, itchy skin

In a hyperglycaemic state, blood glucose can rise to the level that the amount of glucose filtered exceeds the tubular cells’ capacity for reabsorption, which results in glucose appearing in the urine (glucosuria). Glucose in the urine exerts an osmotic effect that draws water with it, producing an osmotic diuresis characterised by polyuria. The excess fluid lost from the body leads to dehydration. This results in polydipsia, a compensatory mechanism to counteract the dehydration. Prolonged high blood glucose causes glucose absorption and changes in the shape of the lens in the eye, leading to vision changes.

Because patients with DM2 have sufficient insulin concentrations to prevent lipolysis, there is usually no history of ketosis except in situations of unusual stress (e.g. infections, trauma). Furthermore, weight loss is uncommon in these individuals because relative high endogenous insulin levels promote lipogenesis. Commonly, macrovascular disease is evident at the time of diagnosis; occasionally, microvascular complications that suggest the presence of undiagnosed or subclinical DM for 7 to 10 years are evident as well.
1.9.7 Prognosis
DM2 is associated with a number of long-term complications. These longer-term sequelae of DM account for most of the morbidity and mortality in the diabetic population. Complications are typically assigned to macrovascular or microvascular complications. DM2 is one of many risk factors for macrovascular disease (cardiovascular disease, stroke, peripheral vascular disease). Glucose toxicity appears to contribute most to the development and progression of microvascular complications, which include retinopathy, nephropathy and neuropathy. However, epidemiological studies also show a general relationship between degree of glucose control and risk of cardiovascular events [Atsushi Goto et al, 2013]. Thus the primary goal for type 2 diabetic individuals is to bring glucose concentrations as close to normal values as possible. The effect of tight blood glucose control on the cardiovascular and microvascular complications of DM2 was addressed by the United Kingdom Prospective Diabetes Study (UKPDS). [UKPDS Group, 1998] The results of this study dramatically demonstrated that with good blood glucose and blood pressure control, many of the complications of DM can be prevented.

1.9.8 Management of Type 2 Diabetes
i. Current Best Practice
The diagnosis and management of DM2 is supported by a number of guidelines. They include the following:
  - National Institute for Clinical Excellence (NICE) Clinical Guideline: Management of Type 2 Diabetes
Scottish Intercollegiate Guidelines Network (SIGN) Management of Diabetes: A National Guideline

International Diabetes Federation (IDF) Global Guideline for Type 2 Diabetes

Institute for Clinical Systems Improvement (ICSI) Management of Type 2 Diabetes Guidelines

The management of DM2 focusses on a number of areas. These include management of blood glucose levels, macrovascular complications (including hypertension and hyperlipidaemia), microvascular complications (including diabetic nephropathy, visual impairment, diabetic foot disease and renal disease) and lifestyle (diet, exercise and smoking cessation). The main goals in the management of DM2 should be as follows:

- fasting blood glucose of 4-6mmol/L
- Glycosylated haemoglobin (HbA1c) <7%
- blood pressure <130/80mmHg
- total cholesterol <4.0mmol/L
- Body Mass Index (BMI) of <25kg/m² where practicable
- cigarette consumption of zero
- alcohol intake of < two standard drinks per day for men and one for women
- >30 minutes walking (or equivalent) five or more days per week

In striving to attain these goals, it ensures patients remain free of symptoms associated with both hyper and hypo glycaemia. Furthermore, it serves to eliminate or minimise macro- and micro- vascular complications. It is also
essential to integrate the patient into the health care team through education. It has been shown that enhanced patient knowledge and understanding of their condition can favourably influence its outcomes. [Hornsten, A, 2005] The some of the non-pharmacological treatments such as:

- Lifestyle Interventions
- Dietary Intervention
- Physical Activity
- Smoking Cessation

1.9.9 Pharmacological Treatment for Diabetes Mellitus

Whilst diet and exercise remains the cornerstone of the management of DM2, with the aim of maintaining ideal body weight and reversing the potentially damaging metabolic consequences, the ability of patients to maintain lower weight and metabolic benefits for prolonged periods is limited and pharmacological therapy is often necessary. A wide range of oral antidiabetic drugs are currently licensed for use in DM2. Furthermore, patients with DM2 are often already taking several other drugs to treat their cardiovascular conditions, dyslipidaemia, hypertension, depression, and other chronic illnesses that come with aging. Ultimately, the aim of therapy should be the simplest, safest regimen that gives the patient the best glycaemic control possible. The various pharmacological treatments are as follows:

- \( \alpha \)-Glucosidase Inhibitors
- Biguanides
• Sulphonylureas
• Non-Sulphonylurea Insulin Secretagogues
• Thiazolidinediones

1.9.10 Complications

Microvascular Complications

Macrovascular Complications

1.9.11 Patient Education on Diabetes Mellitus

Education is considered to be a fundamental part of DM care. People with T2DM have to assume responsibility for the day-to-day control of their condition. It is therefore critical that they understand the condition and know how to treat it. The aim of education for people with DM is to improve their knowledge and skills, enabling them to take control of their own condition and to integrate self-management into their daily lives. Ultimately, education should assist in achieving improvement in control of blood glucose, blood lipids and blood pressure, management of diabetes-associated complications and QoL. It is recommended that structured patient education is made available to all people with DM both at the time of diagnosis and then as required on an ongoing basis, based on a formal, regular assessment of need. Whilst, there is currently insufficient evidence available to recommend a specific type of education or provide guidance on the setting for, or frequency of, sessions, that evidence which does exist suggests that both general and focussed self-management
education for people with DM2 can have a positive effect on glycaemic control [National Institute for Clinical Excellence, 2002.].

The following are some of the laboratory tests available to assess the blood glucose level in the body:

- Glycaemic Control
- Self-Monitored Blood Glucose (SMBG)
- Glycosylated Haemoglobin

1.10 BEHAVIOURAL CHANGE AND PATIENT SELF-MANAGEMENT

1.10.1 Health-related behavioural change: models and theories

There are different theories and models have been postulated to demonstrate health-related behaviours in primary care. [Ogden, J, 2003] The most widely used is: Social Cognitive Theory, Self-regulation, Learning Theories, the Health Belief Model, Self-efficacy Theory, Theory of Reasoned Action, Theory of Planned Behaviour, and the Stages of Change Model. [Clifford, A et al, 2009]

1.10.2 The Stages of Change

One of the key constructs of the TTM is the Stages of Change. Behavioral change can be thought of as occurring as a progression through a series of stages. Previous research has measured a number of cognitive and behavioral markers that have been used to identify these stages. The Stages of Change are as follows:

- Precontemplation
- Contemplation
- Preparation
• Action
• Maintenance

Figure No. 1: Stages-of-change model


1.10.3 Assessment of beliefs, behaviours and knowledge for T2DM selfmanagement

The behavioural, psychological and social status of diabetics can impact considerably on their ability to self-manage their disease. [Green, BB et al, 2008] The diabetes care encounter between patient and healthcare provider creates opportunities for the provider to appropriately assess or screen patients for aspects of their psychosocial status and health-related behaviours
and pharmacists are well positioned to measure certain key psychosocial variables using validated scales. [Craig W. Spellman, 2009] There is a comprehensive array of screening tools available that may be used in behavioural and psychosocial screening in primary healthcare settings.

Behavioural and psychosocial screening in DM2 includes, but is not limited to, the patient issues of health beliefs, attitudes about the disease, expectations relating to diabetes care provided by healthcare professionals, satisfaction with care, planning diabetes care, self-management practices and behaviours, including adherence, knowledge and understanding of key aspects of the condition, empowerment, self efficacy, coping skills, problem solving, social support and depression. [JoAnn R. Gurenlian et al, 2012; Karen Siegel et al, 2008]

1.10.4 Assessment of health-related beliefs

Adherence to prescribed pharmacotherapy is strongly influenced by the patient’s perception of the necessity of taking medicines versus any concern the patient may have about possible adverse effects associated with using the medication. [Horne, R and Weinman, J, 1999] Researchers have used a variety of instruments to measure patient medication-related beliefs, with the most popular in recent times appearing to be the Beliefs about Medicines Questionnaire (BMQ), which consists of two parts. The first section considers patient beliefs in terms of the key adherence-related domains of necessity and concerns about the medication prescribed for the patient. The second part of the questionnaire refers to patient perceptions in general about the harm that medicines may cause and the possible
overuse of medicines by medical practitioners. The BMQ may identify aspects of the patient’s medication belief construct requiring clarification or remedial intervention. [Horne, R, et al, 1999]

Patient satisfaction, together with understanding aspects of the disease and recall ability plays a pivotal role in the adherence dynamic. Patient satisfaction correlates positively with therapeutic persistence and adherence and to intermediate health outcomes in chronic disease management. [Akinori Hisashige et al, 2013; Syed W Gillani et al, 2012] It is also a measure of healthcare provider competency. Various scales have been developed to measure patient satisfaction including the Patient Satisfaction Scale, which has three subscales: technical, information and patient support, and the 17-item Satisfaction with Information about Medicines Scale, which is designed to assess the extent to which patients feel satisfied with the level of information they receive when medication is prescribed. Patient satisfaction, in terms of specific medication experiences, has been investigated by the Treatment Satisfaction Questionnaire for Medication. [Miguel A MJ et al, 2008]

1.10.5 Assessment of health-related behaviours

The significant behavioural and lifestyle changes demanded of diabetes patients places the patient and the patient’s social support structure (relatives or friends) at the centre of the collaborative treatment continuum. [Anne Kennedy et al, 2013; Hunt, D, 2001] As self-management adherence is strongly associated with diabetes-related attitude, an improved understanding of this behaviour may assist in the design and implementation of diabetes self-management plans. [HK Al-
Tools that have been used to assess diabetes self management include the Summary of Diabetes Self-Care Activities self-report which, because of the multidimensional nature of diabetes self-management, assesses each component separately rather than by combining scores across components. Other self-report scales such as the Diabetes Regimen Adherence Questionnaire have, however, combined scores in different areas in order to produce a total adherence score. [HK Al-quazaz et al, 2010]

The value of patient self-reported adherence is well documented, despite being associated with an overestimation of adherence. [Luis-Emilio García-Peñez et al, 2013] The literature concerning medication adherence is voluminous and a number of instruments have been developed to assess this important variable. Among the instruments that appear to be more commonly used is the Morisky Medication Adherence Scale consisting of four items, each requiring either a yes or no answer, [Chapman, RH et al, 2010] or the Medication Adherence Report Scale (MARS). [Horne, R, 2001] The latter instrument is a 5-item scale used to examine self-reported medication use in five medicine adherence domains: forgetfulness, dose alteration, discontinuing therapy, intermittent use of medication and dosage reduction.

1.10.6 Assessment of diabetes-related knowledge

Glycaemic control is associated with diabetes knowledge across different age groups and levels of literacy. [Riethof, M et al, 2012] Instruments used to assess patient knowledge of diabetes include the Diabetes Knowledge Scales, [Dunn, SM et al, 1990] the Spoken Knowledge in Low Literacy in Diabetes Scale [Kelly Marvin
Jeppesen et al, 2012] and the Brief Diabetes Knowledge Test which was designed by the MDRTC as a 23-item diabetes knowledge questionnaire. The first part of the MDRTC instrument consists of a 14-item general diabetes knowledge test which includes four questions about diet, six that are glycaemia related and four relating to knowledge about aspects of the more common complications of diabetes. The second part is a 9-item insulin-specific test. [HK Al-quazaz et al, 2010]

The Understanding Self-management Practices Scale, a 10-item sub-scale of the Diabetes Care Profile, is derived from the MDRTC’s Understanding Management Practice. [HK Al-quazaz et al, 2010] Patients are asked if they had received diabetes education, and if so then to rate their understanding of the following cardinal aspects of diabetes self-management: diet and glycaemic control, management of body mass, physical exercise, medication use, adherence to pharmacotherapy, foot care, diabetes-related complications, eye care, SMBG, and alcohol consumption. The IDF guideline recommends that patients using insulin structure SMBG in line with their insulin therapy. For those patients using oral agents only, the IDF is less prescriptive about SMBG but recommends that it should be ongoing and used to assess glycaemic control, especially for potential hypoglycaemia, in instances where modification to lifestyle and medication therapy occur, and in times of concurrent illness. The ADA suggests SMBG of three or more times daily for patients on multiple injections of insulin.
1.11 References


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