Editorial

Strengthening diabetes management at primary health level

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"If it were possible to evaluate the loss, which this country annually suffers through the avoidable waste of valuable human material and the lowering of human efficiency through malnutrition and preventable morbidity, we feel that the result would be so startling that the whole country would be aroused and would not rest until a radical change had been brought about"

Sir Joseph Bhore, Health Survey and Development Committee report, 1946

Endemic Diabetes: India's Challenge, India's Response

The above words, written on the cusp of independence, ring true even today, 70 years later. Though morbidity patterns have changed, the Bhima-esque scale of health-related challenges facing our nation has not. Replace "malnutrition" with "diabetes", and this sentence provides an accurate description of modern India. Diabetes has become endemic to India.[1] Considering the significant burden of disease, and its complications, it becomes imperative to tackle diabetes at the primary care level. Today most diabetes care in India is provided by the private sector, but given the need for early screening, large numbers of those with pre-diabetes and diabetes mellitus and significant out-of-pocket expenditure incurred by patients there is a clear need for active involvement of public health system. The integration of preventive and curative aspects of medicine at all levels of care, setting up of primary health centers, and changes in medical education to have a field force of "social physicians", owe their existence to the pioneering recommendations of Sir Joseph Bhore. While India has a robust public health care system which caters to the vast majority of its citizens, providing preventive and curative services at primary, secondary, and tertiary levels, control of non-communicable diseases is still in its infancy. The Government of India has addressed the challenge of non-communicable diseases in a big way, yet this program needs to be strengthened and primary health care physicians need to be empowered to prevent and manage diabetes. This will have a huge impact on morbidity and mortality of diabetes.

Various public health initiatives have an impact on the public health delivery of non-communicable diseases in India. The National Rural Health Mission completes 10 years of existence this year.[2] It Seeks to provide effective health care to the rural population, the mission works in tandem with various national health programs, including the National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDS), which was approved in 2010. The Indian Public Health Standards (IPHS) are a comprehensive set of documents which describe uniform standards for health care delivery in India.[3] These standards, first published in 2007, and revised 5 years later, are utilized as an accepted reference for public health planning.

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The IPHS are supported by the National List of Essential Medicines (NLEM) (last revised in 2011),[4] which is based upon the World Health Organization (WHO) LEM (updated in 2013 October).[5] The NPCDS provides detailed operational guidelines, which list responsibilities of staff at various levels of health care, along with an indicative list of useful drugs.[6] The IPHS and NPCDS focus on preventive strategies, evident at all levels of care, is commendable.

The field of diabetes therapy, however, is a dynamic one, whose rate of change is rivaled only by the rise in diabetes prevalence. India has a large pool of pre-diabetics waiting to maintain endemicity by converting to frank diabetes. The age of onset of diabetes is also falling, and primary health care physicians may encounter not only "routine" type 2 diabetes, but also type 1 diabetes, young 2 diabetes with obesity, and gestational diabetes mellitus (GDM). Gestational diabetes offers a unique window of opportunity for us to prevent future diabetes in the woman and her unborn child. Guidelines and recommendations for diabetes screening, diagnosis, and management, therefore, need, to be updated frequently. The most current guidance is provided by the American Diabetes Association and the European Association for Study of Diabetes (2015).[7] Publications from other professional bodies, such as the International Diabetes Federation supplement this information.[8] Indian experts have published recommendations on specific aspects of diabetes care in recent years, but the most recent guidelines on comprehensive diabetes management date to 2005 (Indian Council of Medical Research) and 2007(Association of Physicians of India - Indian College of Physicians).[9,10]

Primary Care Diabetology: A Necessity, A Reality

For the physician working in the public health sector, practicing rational diabetology, within the limitations of the IPHS, the NLEM the WHO LEM, and current international guidelines may seem a challenge. This is not the case at all. This editorial tries to achieve concordance between the various guidelines, and available facilities, while calling for simple revisions in our national standards. It suggests a simple hierarchy of diabetes management, based on easily available, economic and effective drugs, which can be followed at different levels of health care delivery. Bringing this into practice will easily allow management of most diabetes at primary care level.

Diagnostic Facilities

Provision of diabetes care services in various public health systems is compiled in Table 1. While preventive and promotional interventions are available from sub-center level onwards, diagnostic facilities are made available from the primary health center (PHC) upwards. Though some terminology may need modification (e.g. plasma glucose instead of blood sugar), the well laid-out hierarchy of diagnostics is unmistakable. There is a need to harmonize various systems in terms of diagnostics and therapeutics. With the availability of glucometers and much reduced cost of testing strips, there is an opportunity to replace urine sugar with blood glucose testing, even at sub-center level. With the availability of a glucometer, the health worker can screen all pregnant women with a random blood sugar in the first trimester to pick up type 2 diabetics (pregestational diabetics). Alternatively, all pregnant women can be tested with 75 g glucose challenge, in the second trimester, perhaps at the visit used to administer tetanus toxoid. A glucometer reading of >140 mg% can be used to diagnose GDM.[11]

Glucose Lowering Drugs

There is minor discordance, however in the drugs listed in IPHS, NLEM, WHO LEM, and NPCDS. Some of these issues have been raised earlier in the editorials of IJEM.[12] These issues are linked more to the nomenclature of drugs, rather than to the actual science of pharmacology. In essence, almost all these documents envisage availability of a sensitizer, a secretagogue, prandial and basal insulin. The Indian lists include premixed insulin as well. We confine ourselves here to the crafting of a simple treatment algorithm, which is congruent with the overall spirit and philosophy of the national health system.

The drugs listed in the NLEM and IPHS are adequate for the management of the vast majority of people with diabetes. The choice of sulfonylurea needs to be revised, keeping modern advances in mind. Modern sulfonylureas are already listed in the state lists of essential medicines of Madhya Pradesh, Haryana, and Gujarat, among others.[13-15] A sensitizer (metformin), a safe secretagogue (preferably a modern sulfonylurea, viz, glipizide, gliclazide or glimepiride), a rapid-acting insulin, premixed insulin, and basal insulin are enough to achieve glycemic control in most persons. The insulins listed are adequate to manage type 1 diabetes and gestational diabetes as well, though a case may be made for listing insulin analogs as essential drugs, too.

Glucose Lowering Regimes for Various Levels of Care

The regimes that can be crafted with these drugs are in line with those recommended by international guidelines. Table 2

Table 1: Diabetes care at various levels of public health delivery

Level (NLEM)	Primary		Secondary	Tertiary	
Level (IPHS)	Sub center	PHC	CHC	SDH	DH
Manpower	Health workers	At least one MBBS	1 MD/DNB general medicine	At least one MD/DNB general medicine	2–5 MD medicine (based upon bed strength), 1 dietician
Responsibilities	Health promotion	+ treatment	+ diagnosis and treatment	Diagnosis and treatment of DM; refer GDM if necessary	
Diagnostics	Blood sugar	Blood sugar	Urine acetone; blood sugar	Urine acetone; blood sugar	Urine acetone; blood sugar; glycosylated hemoglobin
Oral drugs (NLEM)	Metformin 500 mg Glibenclamide 2.5, 5 mg				
Oral drugs (WHO)	Metformin 500 mg Gliclazide				
Insulin (NLEM)	Soluble, intermediate Premix 30-70				
Oral drugs (IPHS)		Glibenclamide 2.5,5 mg Metformin 500 mg	Daonil 5 mg Metformin 500 mg	Biguanide, chlorpropamide 100 mg, tolbutamide 500 mg, glibenclamide	
Insulin (IPHS)		Soluble insulin	Insulin, insulin zinc suspension	Insulin Lente basal Inj insulin rapid, Inj cry insulin Inj mixtard (desirable)	
Oral drugs (NPCDS)	Metformin				
Insulin (NPCDS)	Insulin regular, insulin intermediate				
Suggested availability (by authors)	None	Metformin, premixed insulin, basal insulin sulfonylurea	Metformin, sulfonylurea, alpha glucosidase inhibitor, pioglitazone; metformin+sulfonylurea FDC; all insulin		

All generic and trade names are listed exactly as mentioned in various documents. NPCDS: National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke, NLEM: National List of Essential Medicines, WHO: World Health Organization, IPHS: Indian Public Health Standards, PHC: Primary health care, CHC: Community Health Centre, SDH: Sub-divisional Hospital, DH: District Hospital, FDC: Fixed dose combination

Table 2: Glucose-lowering regimes, based upon drugs included in NLEM

Essential glucose-lowering regimes	Hierarchy of use	Level of use
Oral regimes		
Metformin	Step 1	PHC and above
Metformin+sulfonylurea	Step 2	PHC and above
Oral+insulin combination		
Met+basal insulin	Step 2	PHC and above
Met+SU+basal insulin	Step 3	CHC and above
Met+premixed insulin (o.d or b.d)	Step 2	PHC and above
Met+basal-bolus insulin	Step 4	SDH and above
Insulin regimes, if oral drugs are contraindicated/not tolerated		
Basal insulin	Step 2	PHC and above
Premixed insulin	Step 3	PHC and above
Basal-bolus insulin	Step 4	SDH and above

Pioglitazone may be included as a Step 2 regime, in states which list this drug. PHC: Primary health care, CHC: Community Health Centre, SDH: Sub-divisional Hospital, NLEM: National List of Essential Medicines

lists the various regimes that can be created using the two oral drugs and three insulin, as listed in the NLEM. It stratifies these regimes into four steps. Step 1 and 2 regimes can be initiated at PHC level, while step 3 regimes can be initiated at community health center (CHC) level, and step 4 (intensive) regimes at SDH (sub-divisional hospital)/DH (district hospital) level. Higher centers, e.g. SDH and DH, should also be stocked with useful drugs such as alpha-glucosidase inhibitors and pioglitazone. Some progressive states, such as Madhya Pradesh, for example, already list pioglitazone ion their essential formulary. Fixed-dose combinations (FDCs) should be made available at all levels of care. It must be noted that all these regimes will be effective only if combined with appropriate lifestyle modification.

All possible permutations and combinations need not be addressed at every level of health care. The primary health care provider, for example, may limit his or her prescription to oral regimes and metformin + basal or premixed insulin. This will minimize the risk of hypoglycemia. The primary provider will also be able to follow-up the vast majority of women with gestational diabetes as they require only medical nutrition therapy. Persons, who need more aggressive therapy, e.g. sulfonylurea + metformin + basal insulin, may be referred to a CHC, while those requiring intensive (basal-bolus) insulin regimes may benefit from consultation or follow-up at sub-divisional or DHs. The National Premixed Insulin guidelines provide suggestions for effective glucose management. These can be strengthened by creating simple manuals for public health doctors, describing regimes which can be crafted using available drugs. Suggestions for when to refer a patient to a higher center should also be included [Table 3]. All such guidance should be evidence-based, and be accepted by consensus among leading professionals.[16]

Table 3: Indication for referral of persons with diabetes

At presentation
Type 1 diabetes
Pregnancy with diabetes/GDM
Life-threatening complication, e.g., DKA, cardiac failure
Limb-threatening complication, e.g., diabetic foot
Organ-threatening complication, e.g., acute renal failure
Sight-threatening complication, e.g., sudden reduction in visual acuity
Ketonuria
On follow-up
Nonresponse to dual oral therapy
Nonresponse to basal/premixed insulin
Non resolution of symptoms
Recurrent hypoglycemia
At presentation/on follow-up
Renal impairment, suspected/documented
Hepatic impairment, suspected/documented
Macro vascular complication, suspected/documented
Micro vascular complication, suspected/documented

GDM: Gestational diabetes mellitus, DKA: Diabetic ketoacidosis

Human Resources

A crucial aspect of any health system is the human resource, and many states of the country face shortages of medical professionals at the PHC and CHC level. Further, since the focus of the public health system has been infectious diseases and reproductive and child health, there is a need for skill upgradation, especially when it comes to non-communicable diseases. Availability of MD Medicine physicians at CHC level is often a constraint, hence diagnosis, treatment initiation, and monitoring will all be required to be done by graduate medical officers. Obstetricians may often have to manage GDM without assistance from physicians. These doctors must be equipped to handle this humungous task.

There is a need for information, education, communication material such as diet-charts, and educational material in vernacular languages. In order to ensure continuity in care, inventory management of drug supply is crucial, along with simplification and harmonization of treatment algorithms. Promoting adherence to treatment regimens (including diet, physical activity, and drugs) is a task that will have to be taken up by non-physician health care workers, including nursing, paramedic staff and health educators at all levels. Dietitians need to be posted at CHC level, to help provide nutritional therapy to people with diabetes and other metabolic diseases. Provision and training of human resources at all levels in non-communicable diseases, including diabetes, is hence a continual need of any health system.

Conclusion

It is important not only to achieve congruence between various national documents, but also to ensure similarity of purpose in continuing medical education programs run for public health personnel including doctors and non-physician health workers. The focus of such programs will have to be dietary management, physical activity, and pharmacology. While all personnel should be aware of advances in diabetes pharmaco-therapeutics, emphasis should be on the rational prescription of economical, effective and easily available drugs. Such training should also include safe prescription, with an emphasis on avoidance, early detection, and management of hypoglycemia. Availability of facilities for diagnosis and monitoring of diabetes, and for dietary advice, must also be addressed, along with available of drugs. As mentioned in the IPHS, a glucometer is desirable at every PHC, and at a sub-center level as well. Regular monitoring and management at grass root level will help improve adherence and outcome of therapy. Availability of basic therapeutic interventions will encourage active community participation in preventive activities as well. Concerted efforts, involving all stakeholders, to strengthen and empower the public health sector primary care provider, in health promotion, disease prevention and management, will certainly help reduce the impact of diabetes.

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