Title: Ethical Qualms While Treating Diabetes In Low Resource Areas

Authors and Email Id:

1. Gajanan Phutke: gajananphutke@gmail.com
2. Sushil Patil: drsushil.jss@gmail.com
3. Yogesh Jain: yogeshjain.jssbilaspur@gmail.com

Corresponding Author and Address:

Gajanan Phutke, Senior Resident, Jan Swasthya Sahyog, Ganiyari.

Email Id: [gajananphutke@gmail.com](mailto:gajananphutke@gmail.com)

Address: Jan Swasthya Sahyog, PO & Village: Ganiyari, Tahsil-Takhatpur, Dist- Bilaspur, Pin-495112

Institutional Affiliations:

1. Senior Resident, Jan Swasthya Sahyog, Ganiyari
2. Coordinator, Jan Swasthya Sahyog, Ganiyari.
3. Co-founder, Jan Swasthya Sahyog, Ganiyari

Declaration:

The work is original and it is not being considered for potential publication elsewhere. The work has not been published previously. All authors have contributed significantly to the manuscript and all authors are in agreement with the content of the manuscript.

Financial support: None

Conflict of interest: None

Ethical qualms while treating Diabetes in low resource areas

**Introduction:**

India has the largest number of diabetics in the world. INDIAB study estimates 62 million diabetics in India(prevalence of 7.3%), with higher urban prevalence (11.2%) than rural 5.2%(1).

Jan Swasthya Sahyog (JSS)(People's Health Support Group) runs a rural secondary care hospital situated in central India, also serves as a referral center for a comprehensive community health programme in 72 hard to reach forest villages. We see about 20,000 new patients every year requiring secondary level care. Diabetes Mellitus constitutes 2.5 % of routine new outpatients. Around 450 new patients get diagnosed to have diabetes in a year. Comparable to urban counterparts, 90% of our patients present during adulthood (type 2) and 10% present during childhood and adolescence (type 1 DM). The median age for type 2 diabetes is just under 50. In contrast to urban counterparts, only a third of type 2 diabetes have a BMI greater than 22.5 Kg/M2 (Indian BMI cutoff for overweight(2)) and over a third have a BMI lower than 18.5 Kg/M2 often referred as 'Lean Diabetes'(3).

In retrospective cohort of 1023 patients(2013-2016), 793 (78%) patients were on OHA (oral anti-hyperglycemic agents) and 230 (22%) required insulin. 81% were taking metformin as one of the drug(4).In another prospective random cohort of 250 type 2 diabetes between November 2017 and April 2018, 22% patients with HBA1C of more than 8 had uncontrolled diabetes with complication prevalence for diabetic foot ulcer 14.8 % (95 % confidence interval 10.2 to 19.4%), late nephropathy (elevated serum creatinine >1.2 mg/dl) 14% and peripheral neuropathy 50 %. (Unpublished Data).

Poor glycemic control and increased complications in rural areas are attributed to barriers like poverty, food insecurity, illiteracy, disproportionate allocation of health resources between urban and rural areas, poor screening and preventive services, non-adherence of diabetic management guidelines, lack of available counseling and long distance travel to health services(5). Most of these barriers are structural and lead to ethical dilemmas for rural healthcare provider. Basu et al (6) described under-recognized nature of ethical dilemma in low resource settings focused on drug therapy. We further elaborate structures leading to ethical dilemmas and suggest possible solutions. There is an urgent need to improve understanding of barriers as well as dilemmas to plan and deliver appropriate care for these neglected patients.

Diabetes is a deficiency amongst excess of glucose. Lean diabetes makes us feel that there is a cruel parallel about diabetes at societal and cellular levels. In diabetes, body cells are surrounded by abundant glucose but cannot use it. Similarly, our rural poor live in a country with marked rise in income and material resources, but cannot reap its benefits due to rising socio economic inequity(7). Some dilemmas are not specific only for diabetes but are also relevant to all chronic illnesses such as how to respect patient autonomy and shared decision making when patient has uncontrolled diabetes and deny close follow up with underlying structural financial and geographical constraints? Should one deny care to those unable to adhere with treatment recommendations or continue treatment while accepting long term micro and macro vascular complications? Should we recommend limiting carbohydrate intake with the awareness of unaffordable protein and fat while 80 % of calories consumed are carbohydrates in patients with BMI of 16 Kg/M2 or lower?

**In Diagnosis:**

**Classification- Is Lean diabetes a separate class?** Classifying diabetes type clinically is challenging in presence of undernutrition. Often lean diabetes is misclassified as either Type 1 or Type 2 due to difficulty to conclude whether low BMI is a cause or effect. This leads not only to underestimation of the actual burden of lean diabetes but also delays initiation of insulin. Some authors propose that these “lean” diabetics represent a separate pathophysiological process than that of classic type 1 and type 2 diabetes while others believe it is a variant of type 2 diabetes(8). Should we call lean diabetes as a separate category when WHO has removed it from current classification(3), different from Maturity onset diabetes of the Young (MODY) ? Should all of these people be investigated for chronic calcific pancreatitis? Classification is important as early starting of insulin in them preserves beta cell function for longer duration. Further studies are needed to study causation and mortality reduction in lean diabetes(9–11).

**In Treatment:**

**Balancing Intensive Hyperglycemic Control and Risk of Hypoglycemia:**

A large majority of rural adults with diabetes have to perform heavy manual work with varying seasonal schedules and are unable to control their meal content or the timing (due to job profile and expense). Uncontrolled status of meals leads to swings in blood glucose levels from life threatening hypoglycemia to hyperglycemia. Should these people have different glucose or HbA1C targets than those in areas with better access? Fear of hypoglycemia is an important factor affecting care in presence of underlying high glycemic index rice based diet (leading to rapid blood glucose swings), higher risk of skipping of meals, religious fasts, livelihood work demanding intense physical activity, mistakes in dosing of OHA or insulin and higher infection rates in these population. Often we err on the side of accepting risk of long term micro and macrovascular complications than hypoglycemia with the principle of non-maleficence, at the same time we have to decide against the principle of justice. We do not have evidence if we are doing the right for our patients.

**Frequency of follow Ups:**

We find it difficult to achieve desired glucose control due to patient’s inability to follow up monthly due to financial and geographic barriers. The situation compels us make a difficult choice between accepting patient autonomy and unmet targets of sugar control without clear consensus of unintended consequences of each decision. We wonder about shared decision making guidelines when patients often don’t seem to understand and judge the consequences or are forced to choose less than ideal follow up frequency owing to structural factors like poor socio-economic status and accessibility of services.

**Glucose Monitoring Test and Quality Control:**

Blood glucose can be tested either by finger prick glucometer or venous blood colorimetry. Glucometric checks have the advantage of rapidity of results, ease of technique and of being a point of care test but requires regular calibration. Erroneous results showing falsely low sugar if strips are stored above 30 C are reported(12).Glucometers are recommended in temperate climate only if quality control results are in acceptable range with individualized quality control plan. HbA1c testing has the advantage of monitoring sugar control for last 90 days but is expensive, has a reasonably difficult technique for peripheral laboratory services to provide, requires high level of quality control. High prevalence of iron deficiency (falsely increases HbA1C(13)) and hemolytic anemia like sickle cell disease(falsely reduces HbA1C(14)) is common in rural India makes its interpretation difficult. In a situation where expenses are paid by patients, physicians have to ensure affordable care or expect high default rates and thus face a dilemma in choosing monitoring tool for sugar control. We worry about escalating therapy based on results of glucometric sugar control without regular calibration or HbA1C results with anemia prevalence being 54%(15).

**Challenges around Insulin:**

OHAs are the mainstay for type 2 diabetes, however a large proportion of type 2 and lean diabetes patients require insulin in doses that sometimes reach 100 IUs a day. We have not been able to find a single satisfactory method of choosing the dose of insulin. Since the overwhelming majority of people consume more than 80% calories as carbohydrates, much higher than published 65 %(16), normal glucose values become difficult to target for. The decision to start insulin in addition to OHAs is painful because of problems related to insulin cost, injection technique, dosing and insulin storage, poor access. In Chhattisgarh and Madhya Pradesh, NPH insulin or Combination (70/30) insulin are rarely available in health facilities other than district hospitals. Maintaining insulin potency in rural setting without electricity and refrigerator is difficult. Earthen pots storage is a poor option in tropical situations with room temperatures beyond 30 degrees Celsius for some hours each day. Ensuring patient's understanding around injectable devices, dosing, reusing and disposing syringes demands extraordinary nursing and counseling skills.

**Lean Diabetes:**

The pathogenesis of ‘lean diabetes’ is multifactorial and the usual standard type 2 diabetes management guidelines are inappropriate for them. Studies from west (17) reports diabetes with normal BMI are at risk of higher mortality than obese counterparts with non-cardiac causes. A hospital based Indian study(18) reports ischemic heart disease, infections, nephropathy, stroke and coma as causes of mortality and should be further studied by community based studies in low resource areas. There is no definite answer about role of weight reduction in lean diabetes (9). Guidelines about prescribing statins need to be redefined in presence of non-obese (lean) diabetes and higher than normal cardiovascular risk in South Asians than rest of the world coupled with limited access to lipid testing. Research on lean diabetes is almost static since 1991 like many other diseases of poor people.

**Dietary and Lifestyle Advice:**

We find this as the most difficult aspect of diabetes management. It is ironical to advise low carbohydrate diet when it constitutes more than 80% of food, Public Distribution System (PDS) providing mainly carbohydrates containing food items and unaffordable proteins and vegetables for poor patients. We are unsure if physicians should advocate for change in PDS food contents for people with diabetes. Should PDS rethink on its content when high carbohydrates are known to increase the risk of diabetes and other non-communicable diseases in general population as well? The work profile for farmers and farm laborers does not allow them to have frequent and small quantity meals. Also guidelines are required for modifying exercises and for optimizing weights in hard working labouringpopulations so as to allow physical labor without adverse effects.

**Type 1 Diabetes:**

Teaching self-glucose monitoring with carbohydrates counting is difficult with poor literacy levels of patients, expensive glucose strips and hypoglycemic risks. In our view just free or subsidized insulin is not enough for their care and health system should also think of psychological trauma, physical disability and invest to make them self-sufficient providing school scholarship and professional skill building. Similarly our system needs to be equipped to allow and engage these rural young patients requiring chronic care in monitoring of health facilities, patient based advocacy and peer support for wider benefit and empowerment.

**Underlying structures leading to Dilemmas:**

For complete understanding of dilemmas, underlying structures of poverty, disproportionate rural health infrastructure, illiteracy, rural culture and their impact on the diabetes care should be taught to rural health workers. We need a paradigm shift from blaming patients for poor adherence to improving health systems.

**Cost of Care:**

Often people with diabetes spend more than 40 % of total household income on care(19). The chronicity of the disease pushes people below poverty line. Thus far there is no insurance coverage for the outpatient level diabetes care. The National program promises affordable care but medicines are not available below the level of CHC, being prescribed for 1 or 2 weeks per visit resulting in almost equivalent expenditure on travel and opportunity cost. The primary health center (PHC) level is not yet implemented on ground in national diabetes care programme(20). Equipping PHCs for follow up care with free investigations and free medicines would help resolve distance and cost barriers of care access.

**Distance**

We find distance from health facilities a common reason for default. Almost all diabetes defaulters require costly emergency and/or inpatient care for complications. Should we have active follow ups by VHW (village Health Worker) for such patients similar to TB? Costing studies would help to understand cost-effectiveness of active follow up approach for health systems.

**Social Stigma and Discrimination**

We often come across social discrimination and stigma associated with diabetes leading to cessation of treatment. Children with type 1 diabetes often drop out of schools or hostels for teacher advising parents to not send child to school for hypoglycemic seizures. Young women presenting with DKA due to discontinued insulin after marriage is not uncommon. Patients often miss their insulin doses when they have to travel outside their home to stay with relatives to avoid stigma. A health system should prevent and protect social discrimination especially for type 1 diabetes for marriage, domestic violence attributed to pregnancy related complications, inability to do equally heavy physical labor?

**Way forward:**

**Diabetes Control Programme:**

We need further studies to answer about how far should communitization of care of diabetes should reach- at VHW, PHC or CHC for better compliance without harm? Can we task share care of diabetes with mid-level health workers or nurses and patient support groups for diabetes on ethical principles? With the onset of diabetes at earlier age, what age group cut offs should be used for population screening in addition to opportunistic screening? How should we handle prediabetes when follow up is not guaranteed? Which method should be used for mass screening? Should we investigate all pregnant women in non-obese environment for gestational diabetes screening?

**Diabetes Education and Support Groups:**

Good patient education material is not available in most vernacular languages. Running peer support groups is one effective strategy in diabetes care(21). They are difficult to organize and get ignored in a resource poor setting. People with skills of counselling are not available where they are needed the most and the task of counselling is left with already burdened doctors and nurses. NPCDCS is currently using mDiabetes (22) with only text messages, the scope of which can be expanded to voice interactive applications for uneducated diabetes patients and caregivers. Mobile technology can also help to form peer support groups.

**Nurse Led Model of Multidisciplinary Integrated Care:**

Technically, management of diabetes is complex, especially with complications. It requires a multidisciplinary approach with physician, nurse, counselor, dermatologist, ophthalmologist, dietician and often a surgeon. Some people with diabetes and certain diabetes syndromes may require consultation with endocrinologist. In the current national programme NPCDCS, specialist care is available at district level and above. We need to have well tested protocols, continued rather than just one time training, continuous guidance for peripheral health workers using mobile technology and referral services for surgical needs in diabetes to compensate for lack of multidisciplinary teams. We need to learn from countries like Rwanda and South Africa (23,24) to aim and achieve nurse led model of NCD care.

**Conclusions**

Diabetes care in low resource rural areas is compromised by barriers of access and finances leading to physician ethical dilemmas. Underlying structures of poverty, disproportionate rural health infrastructure, illiteracy, rural culture should be taught to rural health workers will help in paradigm shift from blaming patients to improving health systems for poor adherence. NPCDCS needs restructuring to contain barriers via communitization of care to with PHC level NCD clinics, task shifting to nurses, health workers by set protocols, continuous training and use of telemedicine and mobile technology so as to allow more physician time and research for complicated cases. Non physician health workers can be utilized better to handle diabetes epidemic.

**References**:

1. Anjana RM, Deepa M, Pradeepa R, Mahanta J, Narain K, Das HK, et al. Prevalence of diabetes and prediabetes in 15 states of India: results from the ICMR-INDIAB population-based cross-sectional study. lancet Diabetes Endocrinol [Internet]. 2017 Aug 1 [cited 2018 Aug 1];5(8):585–96. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28601585

2. Nishida C. Appropriate body-mass index for Asian populations and its implications for policy and intervention strategies [Internet]. Vol. 363, Lancet. 2004 [cited 2018 Sep 9]. Available from: www.thelancet.com

3. Jain Y. Lean diabetes in rural poor populations—management of this subset of patients needs rethinking - The BMJ [Internet]. The BMJ Opinion. 2017 [cited 2018 Aug 5]. Available from: https://blogs.bmj.com/bmj/2017/09/08/yogesh-jain-lean-diabetes-in-rural-poor-populations-management-of-this-subset-of-patients-needs-rethinking/

4. Patil S, Ghali B, Jain Y. The diabetes we see: description of a retrospective cohort of diabetes mellitus in a referral center in impoverished rural central India. Med Friend Circ Bull [Internet]. 2017 [cited 2018 Aug 5];373–374(Dec2016–Feb 2017):41–4. Available from: http://www.mfcindia.org/mfcpdfs/MFC373-374.pdf

5. Kaveeshwar SA, Cornwall J. The current state of diabetes mellitus in India. Australas Med J [Internet]. 2014 [cited 2019 Jan 26];7(1):45–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24567766

6. Basu S, Sharma N. Under-recognised ethical dilemmas of diabetes care in resource-poor settings. Indian J Med Ethics [Internet]. [cited 2018 Dec 20];III. Available from: https://ijme.in/articles/under-recognised-ethical-dilemmas-of-diabetes-care-in-resource-poor-settings/

7. Hardoon D. An Economy for the 99%: It’s time to build a human economy that benefits everyone, not just the privileged few [Internet]. 2017 [cited 2018 Dec 15]. Available from: www.oxfam.org

8. Das S. Lean Type 2 Diabetes Mellitus : Profile, Peculiarities and Paradox [Internet]. [cited 2018 Aug 8]. Available from: http://apiindia.org/pdf/medicine\_update\_2008/chapter\_12.pdf

9. George AM, Jacob AG, Fogelfeld L. Lean diabetes mellitus: An emerging entity in the era of obesity. World J Diabetes [Internet]. 2015 May 15 [cited 2018 Aug 8];6(4):613–20. Available from: http://www.ncbi.nlm.nih.gov/pubmed/25987958

10. TRIPATHY BB, KAR BC. OBSERVATIONS ON CLINICAL PATTERNS OF DIABETES MELLITUS IN INDIA. Diabetes [Internet]. 1965 Jul 1 [cited 2018 Sep 9];14(7):404–12. Available from: http://www.ncbi.nlm.nih.gov/pubmed/14318588

11. Fekadu S, Yigzaw M, Alemu S, Dessie A, Fieldhouse H, Girma T, et al. Insulin-requiring diabetes in Ethiopia: associations with poverty, early undernutrition and anthropometric disproportion. Eur J Clin Nutr [Internet]. 2010 Oct 28 [cited 2018 Sep 9];64(10):1192–8. Available from: http://www.nature.com/articles/ejcn2010143

12. Pratumvinit B, Charoenkoop N, Niwattisaiwong S, Kost GJ, Tientadakul P. The Effects of Temperature and Relative Humidity on Point-of-Care Glucose Measurements in Hospital Practice in a Tropical Clinical Setting. J Diabetes Sci Technol [Internet]. 2016 [cited 2018 Aug 12];10(5):1094–100. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26908568

13. Christy AL, Manjrekar PA, Babu RP, Hegde A, Rukmini MS. Influence of iron deficiency anemia on hemoglobin A1c levels in diabetic individuals with controlled plasma glucose levels. Iran Biomed J [Internet]. 2014 [cited 2018 Aug 13];18(2):88–93. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24518549

14. Lum G. Artefactually Low Hemoglobin A 1C in a Patient with Hemolytic Anemia. Lab Med [Internet]. 2010 May 1 [cited 2018 Aug 13];41(5):267–70. Available from: https://academic.oup.com/labmed/article-lookup/doi/10.1309/LME5Q0LRZDW4DHJR

15. International Institute for Population Sciences (IIPS) and ICF. NATIONAL FAMILY HEALTH SURVEY (NFHS-4) 2015-16 INDIA [Internet]. 2017 [cited 2018 Aug 13]. Available from: http://www.rchiips.org/nfhs

16. Dehghan M, Mente A, Zhang X, Swaminathan S, Li W, Mohan V, et al. Associations of fats and carbohydrate intake with cardiovascular disease and mortality in 18 countries from five continents (PURE): a prospective cohort study. Lancet (London, England) [Internet]. 2017 Nov 4 [cited 2018 Sep 10];390(10107):2050–62. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28864332

17. Carnethon MR, De Chavez PJD, Biggs ML, Lewis CE, Pankow JS, Bertoni AG, et al. Association of weight status with mortality in adults with incident diabetes. JAMA [Internet]. 2012 Aug 8 [cited 2018 Aug 8];308(6):581–90. Available from: http://www.ncbi.nlm.nih.gov/pubmed/22871870

18. Das S, Mishra RK, Jena BB, Mishra BK, Misra KC, Sarangi B. Mortality events amongst non insulin dependent diabetes mellitus patients in Orissa. J Assoc Physicians India [Internet]. 1991 Jul [cited 2018 Aug 8];39(7):519–20. Available from: http://www.ncbi.nlm.nih.gov/pubmed/1800491

19. Jan S, Laba T-L, Essue BM, Gheorghe A, Muhunthan J, Engelgau M, et al. Action to address the household economic burden of non-communicable diseases. Lancet (London, England) [Internet]. 2018 May 19 [cited 2018 Sep 10];391(10134):2047–58. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29627161

20. Directorate General of Health Services M of H& FW. NATIONAL PROGRAMME FOR PREVENTION AND CONTROL OF CANCER, DIABETES, CARDIOVASCULAR DISEASES & STROKE (NPCDCS) OPERATIONAL GUIDELINES [Internet]. Directorate General of Health Services, Ministry of Health & Family Welfare; [cited 2018 Aug 1]. 66 p. Available from: http://health.puducherry.gov.in/ACTS AND MANUALS/Operational\_Guideline\_NPCDCS.pdf

21. Jain Y, Jain P. Communitisation of healthcare: peer support groups for chronic disease care in rural India. BMJ [Internet]. 2018 Jan 10 [cited 2018 Jun 12];360:k85. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29321150

22. Ministry of Health and Family Welfare. Welcome to mDiabetes... [Internet]. [cited 2018 Sep 10]. Available from: http://mdiabetes.nhp.gov.in/

23. Tapela NM, Bukhman G, Ngoga G, Kwan GF, Mutabazi F, Dusabeyezu S, et al. Treatment of non-communicable disease in rural resource-constrained settings: a comprehensive, integrated, nurse-led care model at public facilities in Rwanda. Lancet Glob Heal [Internet]. 2015 Mar 1 [cited 2018 Aug 12];3:S36. Available from: http://linkinghub.elsevier.com/retrieve/pii/S2214109X15701555

24. Coleman R, Gill G, Wilkinson D. Noncommunicable disease management in resource-poor settings: a primary care model from rural South Africa [Internet]. 1998 [cited 2018 Aug 12]. Available from: http://apps.who.int/iris/bitstream/handle/10665/56298/bulletin\_1998\_76%286%29\_633-640.pdf?sequence=1&isAllowed=y