

International Diabetes Federation (IDF) Position Statement

Bariatric Surgical and Procedural Interventions in the Treatment of Obese Patients with Type 2 Diabetes

Taskforce on Epidemiology and Prevention

Duality of Interest Declaration

The International Diabetes Federation makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel.

Specifically, all members of the writing group are required to declare all such relationships that might be perceived as real or potential conflicts of interest.

The global perspective: The need for this statement



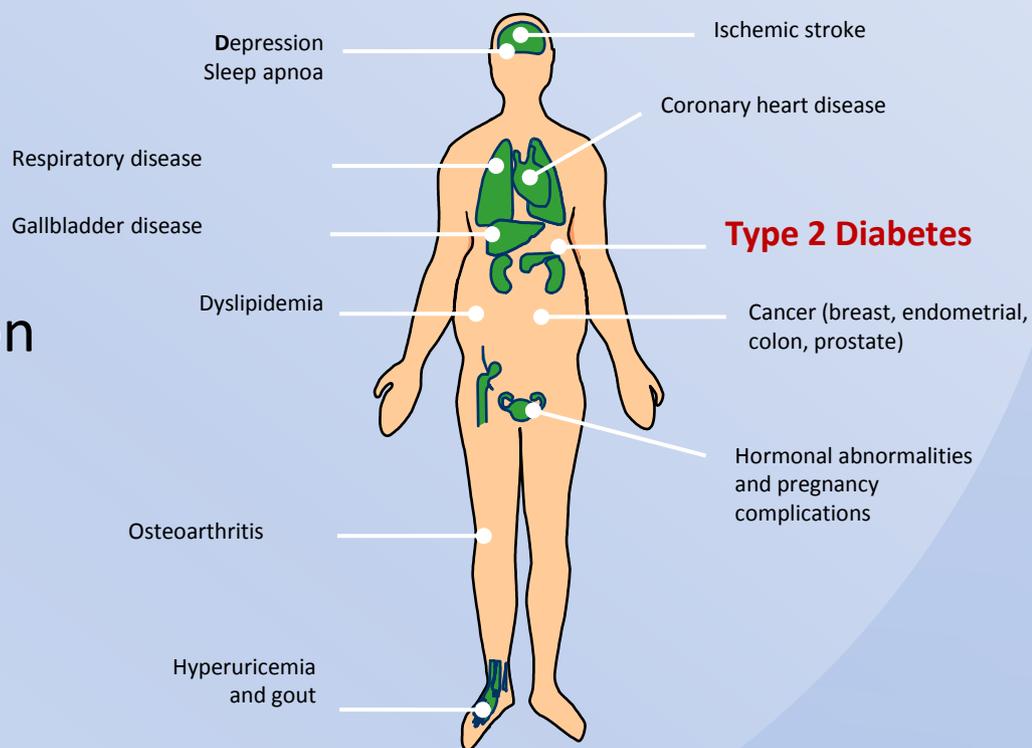
Professor Sir George Alberti

Why?

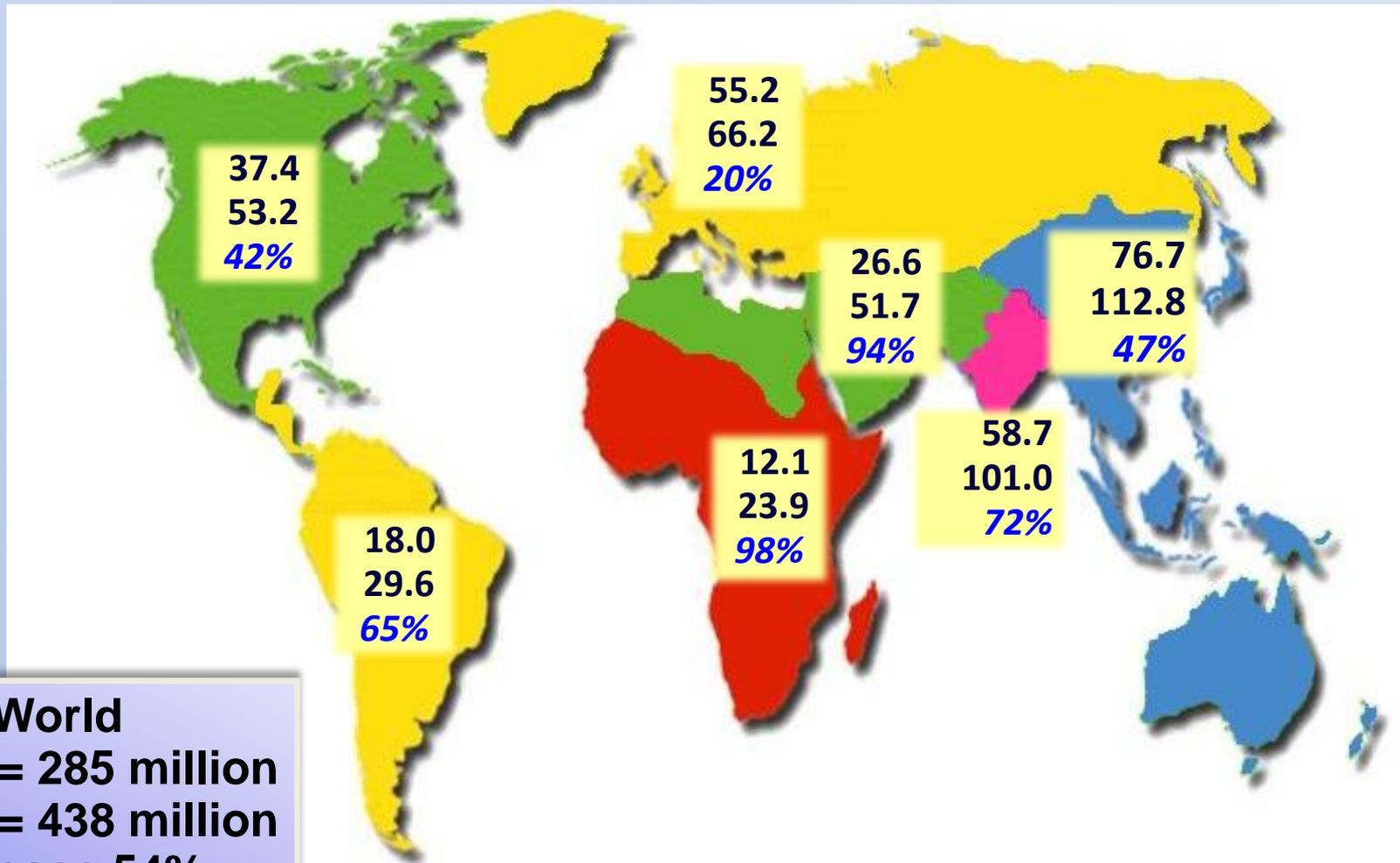
- We are in the middle of a Type 2 diabetes epidemic and the numbers are continuing to escalate. The epidemic is strongly correlated with increases in obesity and physical inactivity.
- The need for strategies to prioritise severely obese persons with type 2 diabetes to ensure that bariatric interventions are available to those most likely to benefit.
- The International Diabetes Federation has not previously considered this rapidly developing area of care for world-wide use.

Obesity: a chronic and complex disorder

- Obesity and type 2 diabetes are serious chronic diseases associated with complex metabolic dysfunctions that increase the risk for ill health and death
- Societal prejudices about severe obesity, which also exist within the health care system, should not act as a barrier to the provision of clinically effective and cost-effective treatment options

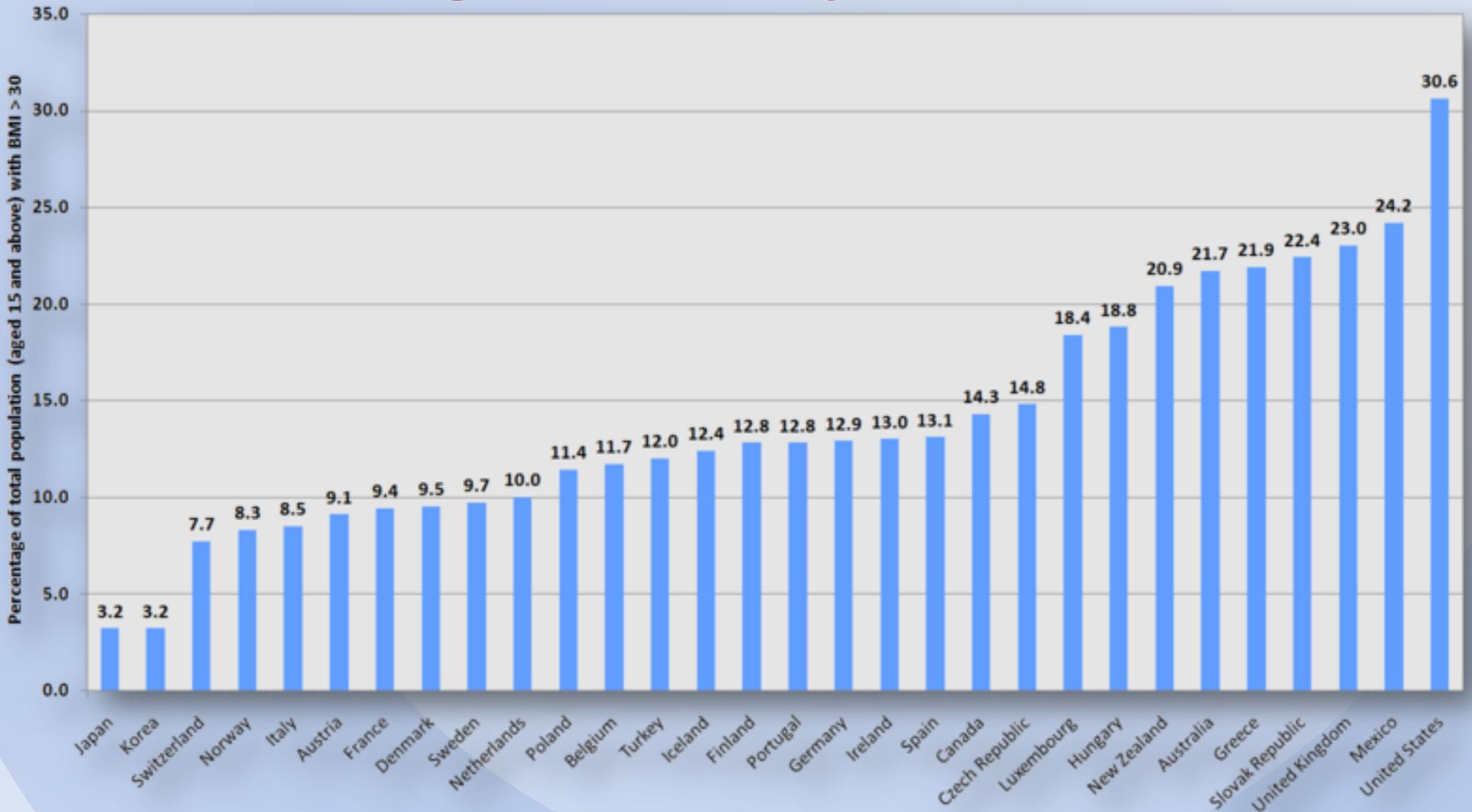


Global projections for the diabetes epidemic: 2010-2030 (millions)

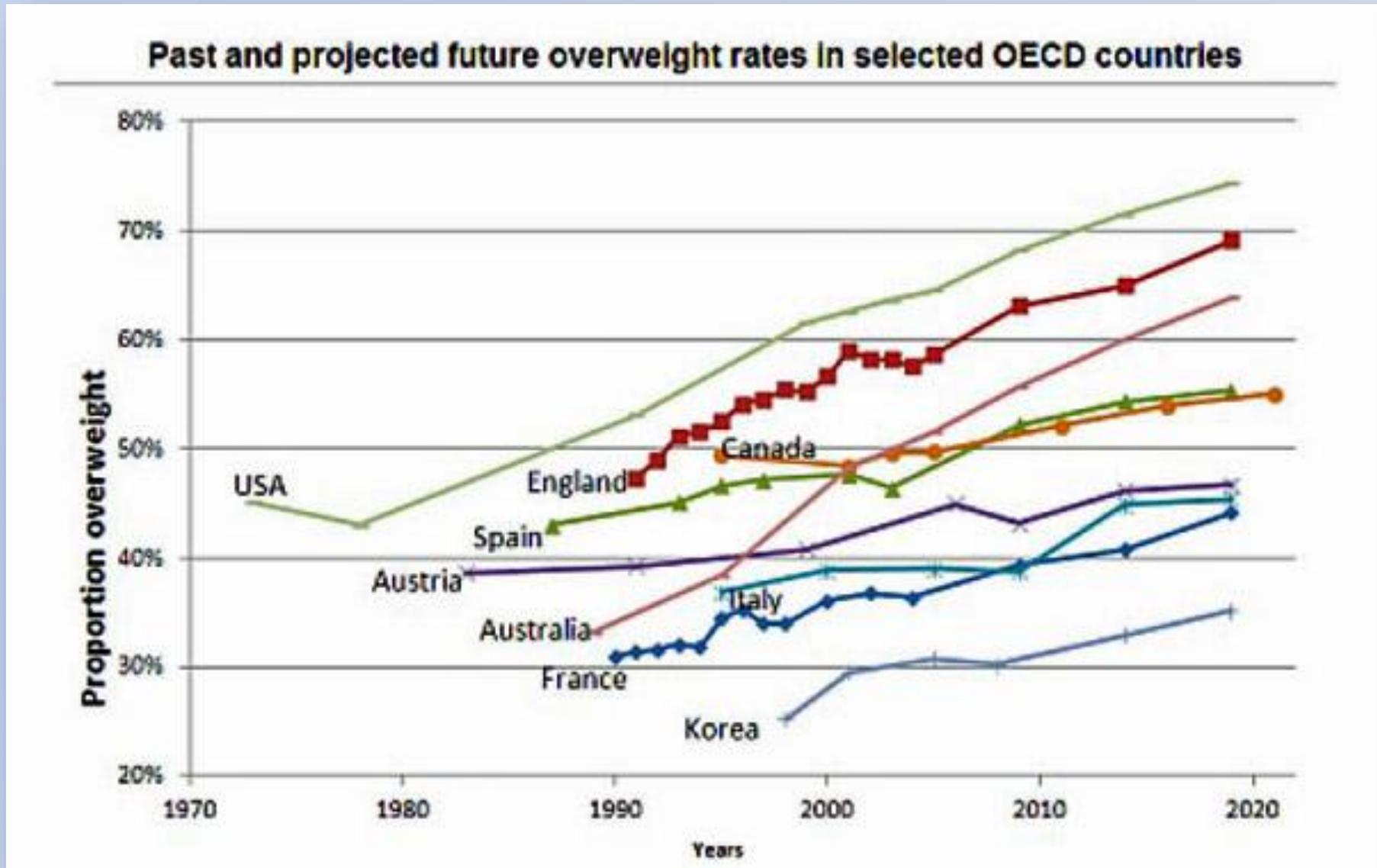


World
2010 = 285 million
2030 = 438 million
Increase 54%

Where do nations rank in the global obesity stakes?



OECD Predictions for Future Overweight Rates



Specific goals of the IDF Position Statement

- Develop practical recommendations for clinicians on patient selection and management
- Identify barriers to surgical access
- Suggest health policies that ensure equitable access to surgery
- Identify priorities for research

IDF Taskforce Consensus Panel

Conveners:

- Professor George Alberti
- Professor John B. Dixon
- Professor Francesco Rubino
- Professor Paul Zimmet

Attendees:

- Professor Stephanie Amiel
- Professor Louise A. Baur
- Professor Nam H. Cho
- Dr. Bruno Geloneze
- Professor Jan Willem Greve

- Professor Linong Ji
- Dr. Muffazal Lakdawala
- Professor Wei-Jei Lee
- Professor Pierre Lefebvre
- Dr. Carel le Roux
- Professor Jean-Claude Mbanya
- Professor Gertrude Mingrone
- Dr. Philip R. Schauer
- Professor Luc Van Gaal
- Dr. David Whiting
- Professor Bruce M. Wolfe

The IDF Position Statement on Bariatric Surgery in obese type 2 diabetes



**International
Diabetes
Federation**

Professor Paul Zimmet AO

Bariatric Surgery: What is it?

- Various types of surgery on the gastrointestinal tract
- Originally developed to treat morbid obesity (“bariatric surgery”)
- Additional to behavioural & medical approaches, it provides an important option for treating type 2 diabetes in severely obese patients
 - often **normalising blood glucose** levels, within days in some procedures
 - reducing or avoiding the need for medications



Bariatric surgery: Which persons with obese type 2 diabetes should be considered?

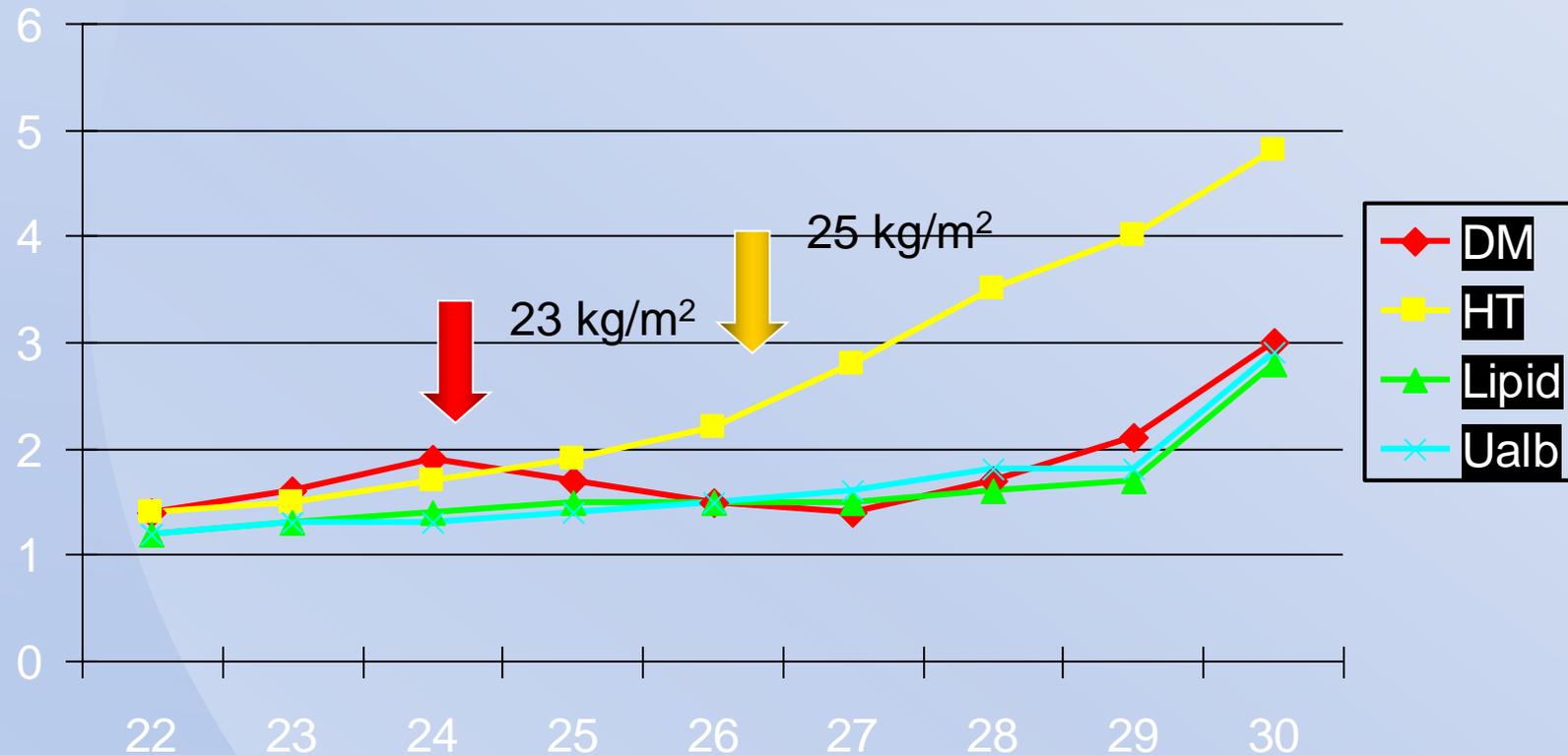
- Bariatric surgery is an appropriate treatment for people with type 2 diabetes and obesity not achieving recommended treatment targets with medical therapies, especially when there are other major co-morbidities.
- Surgery should be an accepted option in people who have type 2 diabetes and **BMI of 35 or more**

Bariatric surgery: Which obese type 2 diabetes should be considered?

- Surgery should also be considered as an alternative treatment option in persons with **BMI 30 to 35** when diabetes cannot be adequately controlled by optimal medical regimen, especially in the presence of other major cardiovascular disease risk factors
- In Asian, and some other ethnicities of increased risk, BMI action points may be lower e.g. **BMI 27.5 to 32.5**



Obesity & Cardiovascular Risk Factors in Chinese Males: Hong Kong



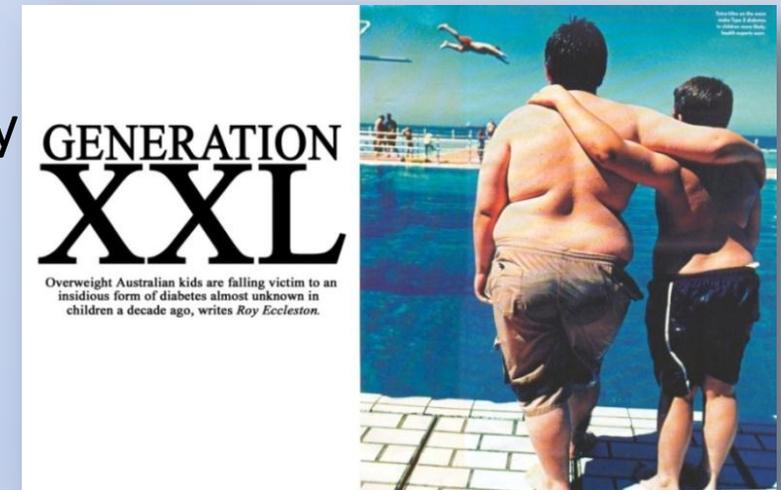
BMI kg/m²

Likelihood ratio for diabetes, hypertension, dyslipidaemia or albuminuria at various BMI (kg/m²) cutoff values

Ko et al. Int J Obesity 1999

Bariatric surgery for obese adolescents with type 2 diabetes

- An Australian report* recommends surgery be considered if adolescents have BMI >40 , or >35 with severe co-morbidities, are 15 years or over & can provide informed consent
- This IDF position statement advises that only 2 procedures, Roux-en-Y gastric bypass & laparoscopic gastric banding are currently conventional bariatric surgical procedures for adolescents



*Baur LA & Fitzgerald DA. Recommendations for bariatric surgery in adolescents in Australia and New Zealand. *J Paediatr Child Health* **46**, 704-707 (2010).

Management Algorithm for Metabolic Control in Type 2 Diabetes

Lifestyle Modification

- diet modification
- weight control
- physical activity

Metformin

Sulphonylurea

Bariatric Surgery

BMI > 35 eligible
BMI > 40 prioritised

Bariatric Surgery

BMI > 30 eligible & BMI > 35 prioritised

*If HbA1c >7.5% despite optimized conventional therapy, especially if weight is increasing, or if other weight responsive comorbidities are not reaching target on conventional therapy.

Acarbose

DPP-4 inhibitor

Glitazone

Insulin

Basal

Premixed

Basal Bolus insulin

Bariatric interventions in low & middle income nations

- The situation in low and middle income nations presents special problems because severe obesity is increasing at an alarming rate
- It is up to each health system to determine whether bariatric surgery with its support services is economically appropriate
- Health care resources are limited so bariatric surgery should only be performed where:
 - the health budget can afford it
 - the expertise is available for both the surgery and the long-term follow up



Factors to consider when choosing a procedure in obese patients with type 2 diabetes

- Expertise & experience in the bariatric surgical procedures
- Patient's preference when the range of risks & benefits, the importance of compliance, & the effects on eating choices and behaviours have been fully described
- Patient's general health & risk factors associated with higher peri-operative morbidity & mortality
- Duration of the diabetes
- The follow-up regimen for the procedure and the commitment of the patient to adhere to it

Tackling “diabesity” globally

- Continuing population-based efforts are essential to prevent the onset of obesity and type 2 diabetes, given the escalating global obesity & diabetes crisis
- At the same time, effective treatment must also be available for people who have developed type 2 diabetes. The available therapies for health care providers are inadequate



Recommendations on surgical management



Professor Francesco Rubino

Recommendations on surgical management I

- Bariatric surgery for type 2 diabetes must be performed within accepted international and national guidelines

This requires:

- Appropriate assessment for the procedure
- Comprehensive and ongoing multidisciplinary care
- Patient education
- Follow-up and clinical audit, as well as safe and effective surgical procedures
- National guidelines for bariatric surgery in people with type 2 diabetes

Recommendations on surgical management II

- Surgery should be considered as complementary to medical therapies to reduce micro-vascular and cardiovascular risk
- Patients should be assessed and managed by experienced multi-disciplinary teams
- On-going and long-term nutritional supplementation and support must be provided to patients after surgery
- A national registry of persons who have undergone bariatric surgery should be established to ensure quality patient care and to monitor both short- and long-term outcomes

Recommendations on surgical management III

- The morbidity and mortality associated with bariatric surgery is generally low, and similar to that of well-accepted procedures such as elective gall bladder or gall stone surgery
- Bariatric surgery in severely obese patients with type 2 diabetes has a range of health benefits, including a reduction in all-cause mortality
- In order to optimise the future use of bariatric surgery as a therapeutic modality for type 2 diabetes, further research is required



Recommendations on surgical management IV

- Apart from conventional procedures now in use new techniques and devices should be explored in research settings only
- Conventional procedures should be standardised. Other techniques, variations and novel devices can be introduced when supported by an evidence base
- New bariatric procedures require robust assessment for their efficacy, safety, and durability using similar principles to those for assessing new drug therapies and having regards to the benefits and risks of established therapy

Recommendations - Surgical

- Regional surgical expertise, multidisciplinary team experience, and documented quality outcomes are important factors in the regional choice of bariatric procedures
- Bariatric surgery for type 2 diabetes must be performed within accepted international and national guidelines. This requires appropriate assessment for the procedure and comprehensive and ongoing multidisciplinary care, patient education, follow-up and clinical audit, as well as safe and effective surgical procedures

Recommendations on diabetes management and future research



Professor John Dixon

Recommendations on diabetes management

- Surgery should be considered as complementary to medical therapies to reduce micro-vascular and cardiovascular risk
- Patients should be assessed and managed by experienced multi-disciplinary teams
- Glycaemic control should be optimised peri-operatively and should be closely monitored after surgery
- It should be recognised that a prolonged period of normalisation of glycaemic control has benefit for diabetes even if there is eventual relapse

Recommendations on diabetes management

- On-going and long-term nutritional supplementation and support must be provided to patients after surgery
- There should be a minimal accepted data set for pre-surgery and follow-up to allow audit of clinical programmes
 - Weight, blood glucose control, assessment for diabetes complications, laboratory measures and medications etc.
- All longitudinal studies should include quality of life as one of the outcomes



Bariatric interventions for type 2 diabetes: research recommendations

- Establish better criteria than BMI for predicting benefit from surgery & define which patients benefit most from which procedures
- Studies needed to establish the benefit of surgery for persons with diabetes & **BMI less than 35**
- Studies needed to establish whether bariatric procedures prevent or slow the progressive loss of pancreas beta-cell function characteristic of type 2 diabetes
- Studies required to document the course of complications after surgery and to establish the long term complications of surgery
- Studies are needed to establish the duration of the benefit of surgery

Bariatric interventions for type 2 diabetes: research recommendations

- Studies needed to establish the mechanisms of the success of surgery
- Studies are needed to establish the long term complications of surgery
- New techniques should be assessed rigorously for efficacy and safety and ideally their mechanisms
- Studies are needed to define the best regimens of diabetes management after bariatric surgery
- It will be important to develop profiles of those who are best candidates for surgery
- Randomised controlled trials are needed to evaluate and compare different bariatric procedures for the treatment of diabetes between themselves as well as emerging non-surgical therapies

Acknowledgments

The IDF consensus meeting was supported with unrestricted educational grants from:

- Allergan Inc, Irvine, CA, USA
- Ethicon, Ethicon Endo-Surgery, Inc, Cincinnati, Ohio, USA
- MetaCure Inc, Mount Laurel, NJ, USA

None of these companies, or their representatives, had any involvement in the development or preparation of this report