Baker IDI
HEART & DIABETES INSTITUTE

Metabolic Surgery Update
Patients selection and choice of procedure

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Disclosures: Professor John B Dixon

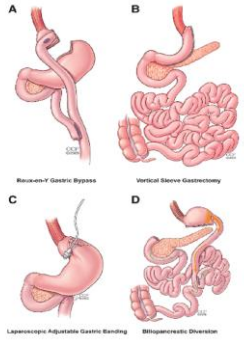
Apollo Endosurgery	Consultant, Research Support
Bariatric Advantage	Consultant, Speakers
BUPA	Research Support
Dendrite Clinical Systems	Speaker fees
I-Nova	Consultancy, Speaker and educational material
Medtronics	Speaker fees and consultancy
Nestle Health Science	Consultant
NHMRC	Research Support
Nova Nordisk	Advisory board and speaker fees
Novartis	Advisory board
Novartis	Advisory board
RACGP	Research Support

Metabolic surgery v traditional Bariatric surgery

- Metabolic surgery – GI surgery designed with the intent to treat type 2 diabetes and obesity
- It requires a diabetes based model of clinical practice consistent with international standards of diabetes care
- Surgery should be performed in high volume centres that understand and are are experienced in the management of diabetes and GI surgery
- Standard procedures should be used

Diabetes Care 2016;39: 861–877

Accepted conventional techniques



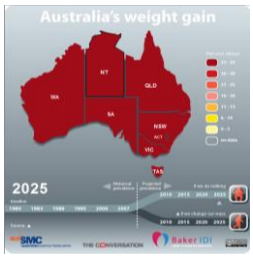
This has always been a clear message from non-surgeons

All have their own risks and benefits

There are now multiple new "diabetes" procedures, however in Australia we appear to be largely followers not leaders in new self-styled variants

Diabetes Care 2016;39: 861–877

BMI trends in Australian adults



2013 Adult Obesity

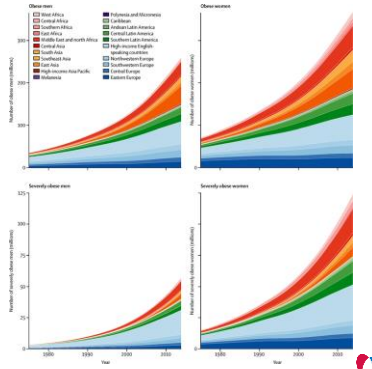
28%

https://theconversation.edu.au/mapping-australias-collective-weight-gain-7816
Walls & Magliano et al, Obesity 2011

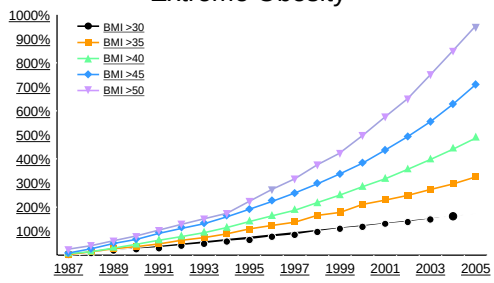
Global & Regional Obesity

High income English speaking
Light Blue

Global & Regional Severe obesity



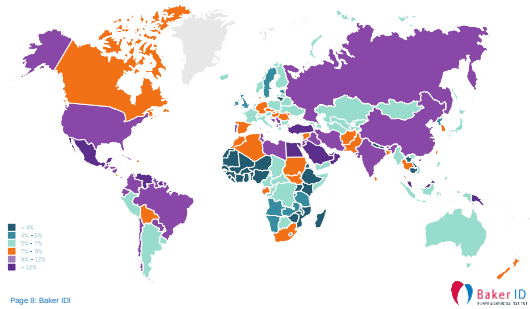
Increasing Prevalence of Extreme Obesity



Sturm R. *Public Health*. 2007;121:492-496.

Diabetes around the world

Estimated age-adjusted prevalence of diabetes in adults (20-79), 2015



Let's look at those with diabetes in Australia

Australian's with type 2 Diabetes 2011

Clinical Terms Used to Describe Various Levels of Body Fat*

NORMAL	OVERWEIGHT	Class I	Class II	Class III
BMI 18.5 — 24.9	BMI 25 — 29.9	BMI 30 — 34.9	BMI 35 — 39.9	BMI ≥ 40
12%	29%	29%	16%	14%

Management and Impact for Long-term Empowerment and Success

* BMI (Body Mass Index): A measurement of an individual's weight in relation to height (kg/m²).

In press Dixon et al, DRCP 2013

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30% in the severely obese categories

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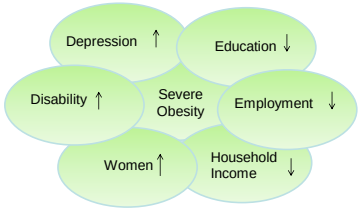
70% Women

30% in the severely obese categories

* BMI (Body Mass Index): A measurement of an individual's weight in relation to height (kg/m²).

The compounding stressors of severe obesity in patients with diabetes



Along with obesity related disease this presents complex management issues

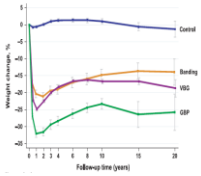
Dixon et al, DRCP 2013

Diabetes MILES Study

SO WHY DO WE NEED SURGERY TO PROVIDE SUSTAINED WEIGHT LOSS AND TREAT OBESITY RELATED COMPLICATIONS LIKE TYPE 2 DIABETES?

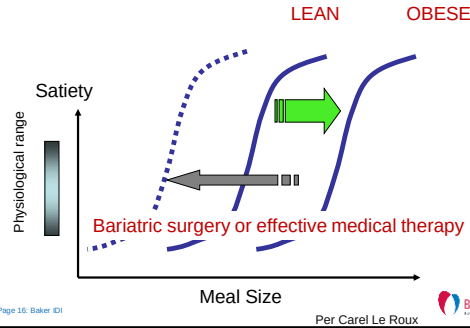
Every essential for a functional life must be carefully regulated

- Temperature
- Oxygen saturation
- Blood pressure
- Blood glucose
- Fuel stores

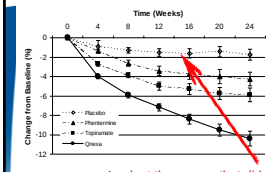


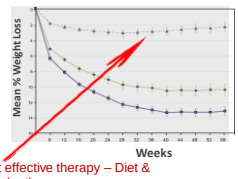
The regulation of energy stores is still working when a obese patient has lost weight following bariatric surgery

Dose response curve "A change in regulation"

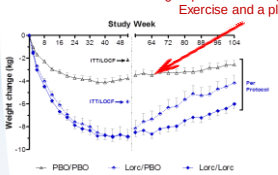


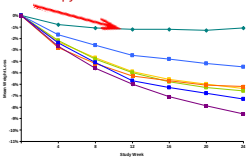
Per Carel Le Roux





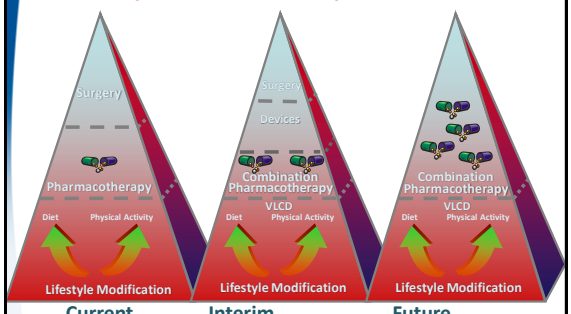
Look at the groups that did not get effective therapy – Diet & Exercise and a placebo therapy



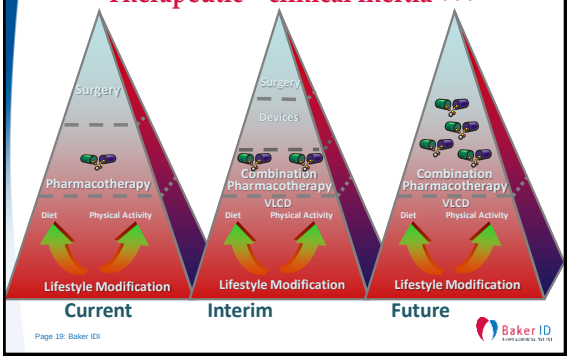


Average weigh for participants is approximately 100kg

Obesity Treatment Pyramid

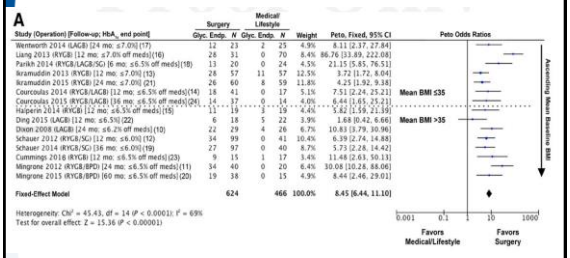


Effective therapies are rarely used
Therapeutic – clinical inertia +++



WHAT IS THE EVIDENCE?

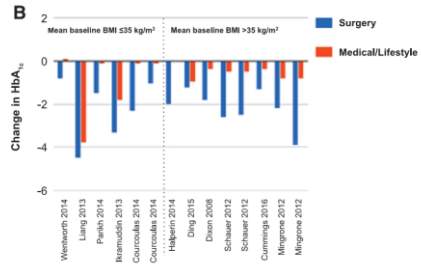
Surgical therapy v Lifestyle-Medical
11 randomized controlled trials



Surgical therapy superior for weight loss and HbA1c

Diabetes Care in press 2016

The evidence – 11 RCTs



Diabetes Care 2016;39: 861–877

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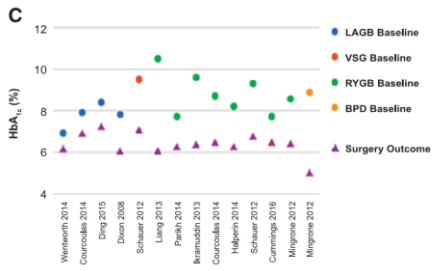

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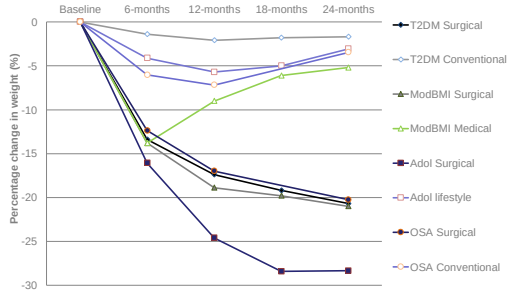
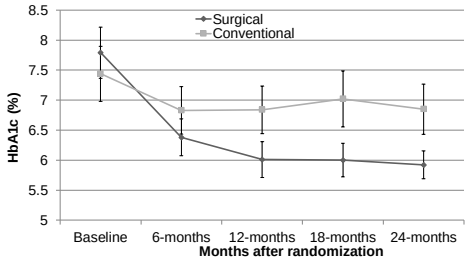
Efficacy – Weight Loss



Ann Intern Med, (2006). **144(9): p. 625-33.** JAMA, (2008). **299(3): p. 316-23;**
*JAMA, (2010). **303(6): p. 519-26;*** JAMA, (2012). **308(11): p. 1142-9.**

HbA1c LAGB 73% v 13% remission



Dixon, J. B., P. E. O'Brien, et al. (2008). "Adjustable gastric banding and conventional therapy for type 2 diabetes: a randomized controlled trial." Jama 299(3): 316-323.

When should Metabolic Surgery be performed?

- The indications for surgery have two levels of eligibility
- Surgery is an option for this patient
- **Surgery is recommended for this patient**
- In the second case a trained caring physician should alert the patients to the recommendation and refer if and when appropriate

The classification of weight category by BMI

All countries use BMI criteria in their criteria for B - D surgery

Classification	BMI(kg/m²)	
	Principal cut-off points	Cut-off points for Asians
Normal range	18.5 - 24.9	18.5 - 22.9
		23.0 - 24.9
Pre-obese	25.0 - 29.9	25.0 - 27.4
		27.5 - 29.9
Obese class I	30.0 - 34.9	30.0 - 32.4
		32.5 - 34.9
Obese class II	35.0 - 39.9	35.0 - 37.4
		37.5 - 39.9
Obese class III	≥40.0	≥40.0

India
China
Singapore
Taiwan
& others have adapted

For Asian populations classifications remain the same as the international classification but that public health action points for interventions are set at 23, 27.5, 32.5 and 37.5

We address eligibility and prioritization for bariatric surgery within the coloured zones above

Source: Adapted from WHO 2004[45]

BMI is an excellent measure of fatness

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

Eligibility and prioritisation for bariatric surgery based on failed non-surgical weight loss therapy, BMI, ethnicity and disease control

BMI Range	Eligible for surgery	Prioritised for Surgery
< 30	No	No
30 –35	YES-Conditional*	No
35–40	YES	YES-Conditional*
> 40	YES	YES

*HbA_{1c} > 7.5 despite fully optimised conventional therapy, especially if weight is increasing, or other weight responsive comorbidities not achieving targets on conventional therapies (e.g. blood pressure, dyslipidaemia, obstructive sleep apnoea)

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

National and international guidelines for eligibility for bariatric surgery (adults)

	NIH (USA)	European	ADA (USA)	SIGN (Scotland)	NHMRC (Australia)	NICE (UK)
Year	1991	2007	2010	2010	2013	2014
Recommended						>50
Eligible (A):BMI	>40	>40	>40		>40	>40
Eligible (B):BMI	35 - 40 with 1 serious weight loss responsive comorbidity	35 - 40 with 1 weight loss responsive comorbidity	35-40 if control of diabetes and comorbidity is difficult	>35 with 1 serious weight loss responsive comorbidity	35 - 40 with 1 serious weight loss responsive comorbidity	35-40 with disease that could improve with weight loss
	Historic				30 -35 If Diabetes is poorly controlled	30 -35 If Diabetes is poorly controlled Within 10 years of diagnosis

The guidelines above are qualified by the following common elements: Appropriate non-surgical weight loss measures have been tried and failed; there is the provision for, and a commitment to, long term follow-up; and individual risk to benefit ratio needs to be evaluated

DSS II

Table 1—International societies that have ratified and/or endorsed the DSS-II consensus statements and guidelines

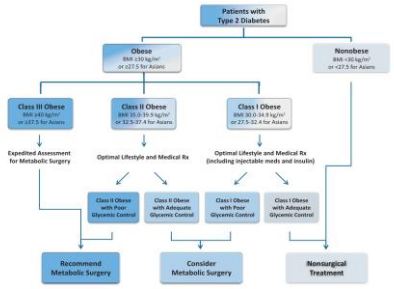
Partner diabetes organizations that helped develop and have ratified the DSS-II consensus statements and guidelines:	Country
American Diabetes Association (ADA)	USA
International Diabetes Federation (IDF)	International
Diabetes UK (DUK)	UK
Chinese Diabetes Society (CDS)	China
Diabetes India (DI)	India

Other organizations that formally endorse the DSS-II consensus statements and guidelines (to date):	
American Association of Clinical Endocrinologists (AACE)	USA
American College of Surgeons (ACS)	USA
American Gastroenterological Association (AGA)	USA
American Society for Metabolic and Bariatric Surgery (ASMBS)	USA
Argentinian Society of Diabetes (SAD)	Argentina
Argentinian Society for Bariatric and Metabolic Surgery (SACO)	Argentina
Asia-Pacific Bariatric and Metabolic Surgery Society (APBMSS)	International
Association of British Clinical Diabetologists (ABCD)	UK
Australian Diabetes Society (ADS)	Australia
Belgian Diabetes Association (ABD)	Belgium
Brazilian Society of Diabetes (SBD)	Brazil
Brazilian Society of Bariatric and Metabolic Surgery (SBCBM)	Brazil
British Obesity and Metabolic Surgery Society (BOMSS)	UK
Czech Society for the Study of Obesity (CSSO)	Czech Republic
Chilean Society of Endocrinology and Diabetes (SCED)	Chile
Chilean Society for Bariatric and Metabolic Surgery (SCCBM)	Chile
Endocrine Society	USA
European Association for the Study of Obesity (EASO)	International
French Society of Diabetes (SFD)	France
French Society of Bariatric and Metabolic Surgery (SOFFCO)	France
German Diabetes Society (DDG)	Germany
German Society for Obesity Surgery (CA-ADIP)	Germany
Hellenic Diabetes Association (HDA)	Greece
International Federation for the Surgery of Obesity & Metabolic Disorders (IFSO)	International
Israel Diabetes Association (IDA)	Israel
Italian Society of Bariatric & Metabolic Surgery (SICOB)	Italy
Italian Society of Diabetology (SID)	Italy
Japan Diabetes Society (JDS)	Japan
Latin American Association of Diabetes (ALAD)	International
Mexican College of Bariatric and Metabolic Surgery (CMCOEM)	Mexico
Mexican Society of Nutrition and Endocrinology (SMNE)	Mexico
Qatar Diabetes Association (QDA)	Qatar
Saudi Diabetes and Endocrine Association (SDEA)	Saudi Arabia
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)	USA
Society for Endocrinology (SfE)	UK
Society for Surgery of the Alimentary Tract (SSAT)	USA
South African Society for Surgery Obesity and Metabolism (SASSO)	South Africa
Spanish Society for Bariatric and Metabolic Surgery (SECO)	Spain
Spanish Society of Diabetes (SED)	Spain
The Obesity Society (TOS)	USA

This table indicates the societies that, at the time this article went to press, had officially ratified and/or endorsed the DSS-II consensus statements and guidelines. Additional international medical and scientific societies are currently considering endorsing these results as well.

Diabetes Care 2016;39: 861–877

Algorithm for the treatment of T2D, as recommended by DSS-II voting delegates



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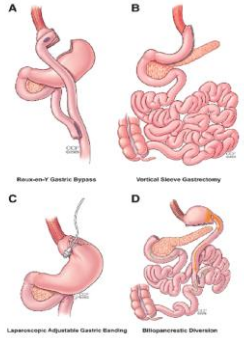
Accepted conventional techniques



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All have their own risks and benefits

There are now multiple new "diabetes" procedures, however in Australia we appear to be largely followers not leaders in new self-styled variants

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	Roux-en-Y gastric bypass	Laparoscopic adjustable gastric band	Biliopancreatic diversion with or without duodenal switch	Sleeve gastrectomy
Mean weight loss (%)	25–35%	20–30%	30–40%	20–30%
Excess weight* loss at 3–5 years[9,15,18] (%)	60% (75% with banded bypass)	50%	75%	50–60% (few reports at ≥3 years)
30 day postoperative mortality[15,17–19]	0·3–0·5%	0·05–0·1%	0·75–1·0%	0·4%†
Major 30 day morbidity[17,43]	Laparoscopic 4·8%, open 7·8%	1%	No data available	No data available
Morbidity at 1 year[2]	14·9%	4·6%	25·6%	10·8%
Pattern of weight loss[7,13,41]	Rapid, maximum at 1–2 years; weight regain at 3–5 years	Gradual, usually maximum at 2–3 years	Rapid, maximum at 1–2 years	Rapid, maximum at 1–2 years
Long-term‡ data available[4,43,45]	Yes	Yes	Yes	No
Evidence of improved survival[4,15,44]	Yes	Yes	No	No
Nutritional concerns	Moderate: deficiencies in iron, vitamin B12, folate, calcium, vitamin D, copper, zinc, and zinc	Low: deficiencies in iron, vitamin B12, and folate	High: deficiencies in iron, vitamin B12, folate, calcium, vitamin D, copper, zinc, and fat-soluble vitamins	Moderate:deficiencies in iron, vitamin B12, folate, calcium, vitamin D, copper, and zinc
Follow-up requirements	Lifelong assessment and nutritional support	Lifelong (high in the first 12 months) band adjustments	Lifelong assessment and nutritional support	Lifelong assessment and nutritional support
Key complications	Abdominal pain, staple-line leak, stomach ulcer, intestinal obstruction, gallstones, nutritional deficiency, weight regain	Gastric pouch dilation, erosion of band into the stomach, leaks to the gastric-band system, weight regain	Abdominal pain, staple-line leak, stomach ulcer, intestinal obstruction, gallstones, nutritional deficiency, weight regain, malabsorption, hypoalbuminaemia, excessive fat malabsorption, progressive liver damage, renal calculae	Staple-line leak, gastro-oesophageal reflux disease, dilation of the gastric remnant, nutritional deficiency, weight regain

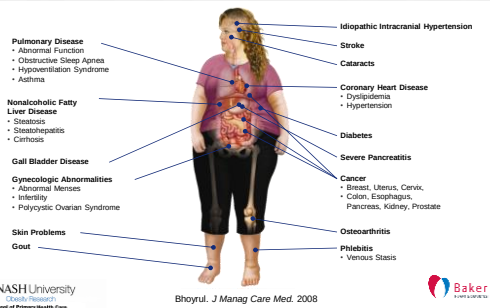
Dixon, J.B., C.W. le Roux, F. Rubino and P. Zimmet, *Bariatric surgery for type 2 diabetes. Lancet, (2012).* ***379(9833): p. 2300-11.***

Surgery is impressive and benefits extend well beyond a glucocentric approach

- Reduced mortality
  - Cardiovascular
  - Cancer
  - Diabetes
- Improved QOL in both physical and mental domains
- Improvement or remission of all obesity related complications
- Highly cost effective especially for diabetes

Obesity Is Linked to a Large Number of Serious Medical Conditions

Obesity-related Co-morbidities[1]



MONASH University Obesity Research School of Primary Health Care

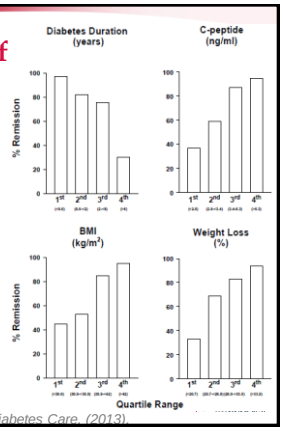
Bhoyrul. *J Manag Care Med.* 2008

Who responds well?

Key determinants of diabetes remission

Gastric bypass
65% remission

- Duration of Diabetes
  - Adequate beta-cell function
- Fasting C-peptide
  - Insulin resistant and adequate beta-cell function
- BMI
  - You must have weight to lose
- (% Weight Loss)
  - You must lose weight



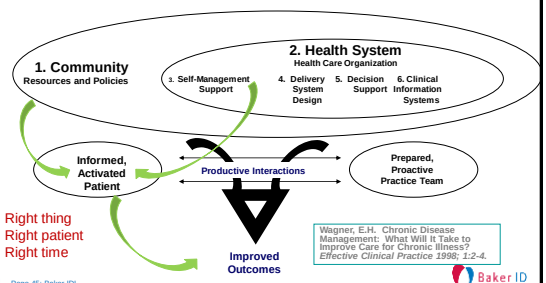
Dixon, J.B., Lee W.J. et al *Diabetes Care. (2013).*

SOS study - IDF Melbourne 2013

- 31% still in remission at 15 years
- Diabetes complications cases v controls
  - Adjusted OR 0.53 (0.37 – 0.76)
- Those with diabetes that had a reduction in micro & macrovascular complications are treated within 3 years of a diagnosis of type 2 diabetes

Peltonen et al, Diabetes remission and complications over 15 years in SOS study IDF 2013

Chronic Care Management Model



Right thing
Right patient
Right time

Wagner, E.H. Chronic Disease Management: What Will It Take to Improve Care for Chronic Illness? *Effective Clinical Practice 1998; 1:2-4.*

The serial accumulation of impressive data

- 2006 Data from 4 studies indicating that bariatric surgery saves lives – Cardiovascular, Diabetes, Cancer.
- The evidence that the risks of surgery have plummeted with the laparoscopic approach and quality training – the technology used in surgery has been revolutionised
- Risk less than gall bladder surgery – No deaths in UK last year.
- The durability of weight loss – SOS and many more
- The 11 randomized controlled trials
- Health economic data – highly cost effective and for those with type 2 diabetes possibly dominant
- Change underway, but the systems to implement the needed changes are not established

Conclusion

- Chronic disease management is integrated health not "medicine v surgery"
- Surgery compliments conventional therapy
- Endocrinologists and diabetologists need to engage bariatric-metabolic surgical teams to assist with the management of their numerous patients who are eligible or prioritized for surgery
- We have done this oncology, other endocrine disorders, cardiology – Why not Bariatric-Metabolic surgery?

Division of Hypertension, Obesity and Stress
Clinical Obesity Research


Gavin Lambert


Markus Schlaich


Toni Rice


Nora Straznicky


Elisabeth Lambert


Mariee Grima