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Reproductive & Sexual Health

Factors associated with the initiation of testosterone replacement therapy among men participating in the 45 and Up study

Dr Yan Cheng, AProf Deborah Bateson, Dr Kristine Concepcion, Dr Mary Stewart, Dr Kevin McGeechan*

* Sydney School of Public Health

Testosterone replacement therapy

Recognised clinical indication

- pathological hypogonadism (eg due to Klinefelter's syndrome, pituitary tumours or surgery/radiation)
  - thought to affect 5 in 1000 men, although many may not be diagnosed.

Disputed clinical indications

- age related decline in testosterone, "Low-T", "andropause"

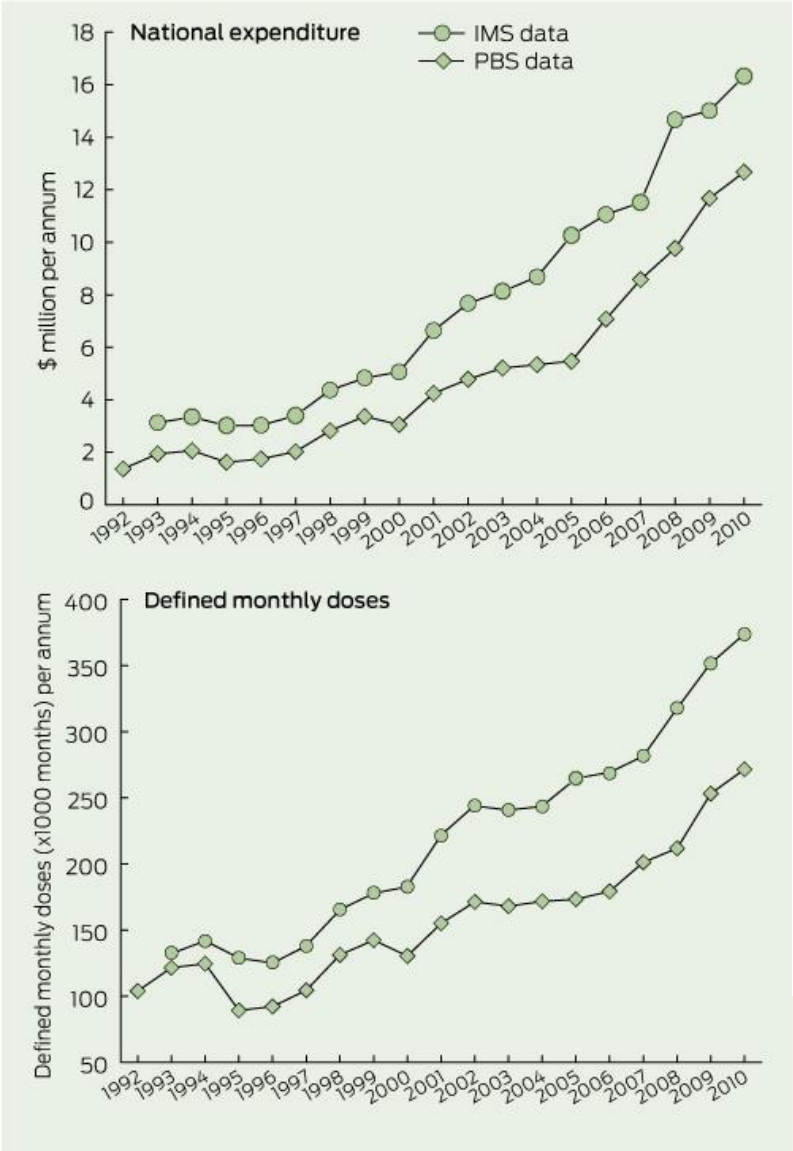
Testosterone replacement therapy

A recent systematic review concluded “The prescription of testosterone supplementation for low-T for cardiovascular health, sexual function, physical function, mood, or cognitive function is without support from randomized clinical trials.” *(Huo, PLoS One 2016)*

Recent NIH sponsored trials of TRT have provided mixed results

- improvements in bone health, hemoglobin levels, sexual function
  - (*Snyder*, JAMA Int Med 2017, *Roy* JAMA Int Med 2017, *Snyder* NEJM 2016)
- increase in indicators of coronary atherosclerosis
  - *(Budoff, JAMA 2017)*
- no effect on cognition, physical function, vitality
  - (*Resnick* JAMA 2017, *Snyder* NEJM 2016)

Testosterone prescribing in Australia 1992 to 2010



Pharmacoepidemiology of testosterone prescribing in Australia, 1992–2010. DJ Handelsman. Med J Aust 2012; 196 (10): 642-645. doi: 10.5694/mja11.11277

45 and Up study

- An ongoing cohort study involving 10% of the New South Wales, Australia, population aged 45 and over.
- Baseline questionnaires were completed in 2006 to 2009
- These data have been linked to administrative datasets on prescriptions filled (Pharmaceutical Benefits Scheme (PBS)), and visits to clinicians and tests ordered (Medicare Benefits Schemes (MBS)).
- We identified men who at the time of the baseline survey did not have a prescription for testosterone replacement therapy in the 2 years before the survey.
- We then examined the factors associated with initiation of TRT in the two years following the survey and whether initiation was consistent with contemporaneous guidelines.

Demographics of participants at baseline (n = 105429)

Age group		
45 to 54	29338	28%
55 to 64	34119	32%
65 to 74	24407	23%
75 and older	17565	17%
Education		
No school cert	10648	10%
School cert	25357	24%
Apprenticeship/diploma	40155	39%
University degree or higher	27562	27%
Area of residence		
Major cities	55602	54%
Inner regional	36011	35%
More remote	11749	11%
Marital status		
Married/de facto	85268	82%
Not married/de facto	19187	18%
Country of birth		
Australia	77455	74%
Other	27077	26%
Current work status		
Paid work	55373	53%
Retired	42608	41%
Other	6770	6%

Testosterone initiation

- 302 out of 105429 (2.9 per 1000) had testosterone initiated in the two years after the baseline survey

- Among these 302 respondents

  – 125 (41%) had an MBS item for a hormone test

  – 180 (60%) visited a specialist before the prescription

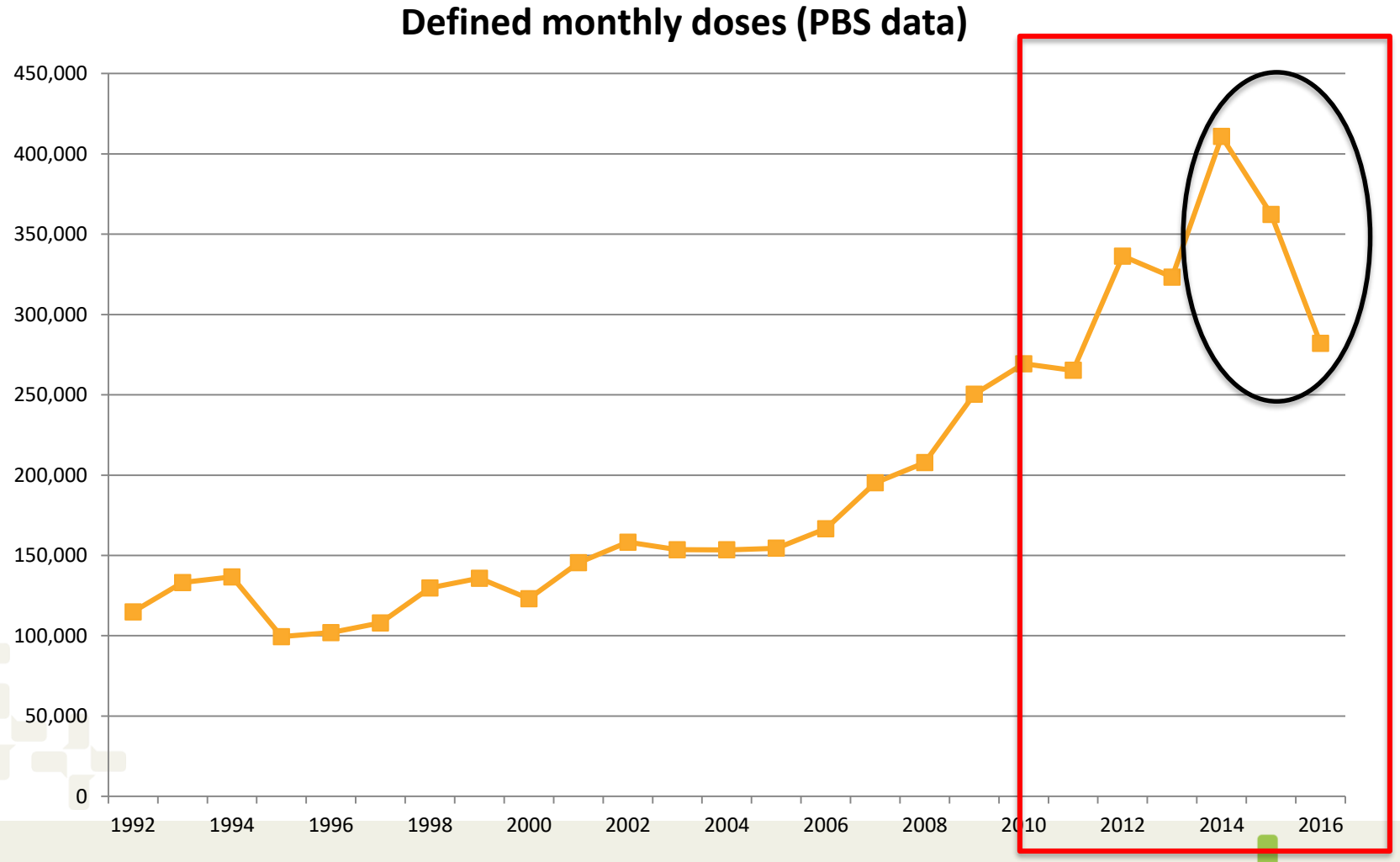
Factors associated with testosterone initiation

Factor	Group	aOR	95%CI	P
Age	45 to 54(ref.)			0.0008
	55 to 64	1.82	1.31-2.51	
	65 to 74	1.72	1.11-2.67	
	75 and older	1.19	0.68-2.07	
Area of residence	Major cities(ref.)			0.0044
	Inner reginal	0.68	0.52-0.89	
	More remote	0.61	0.40-0.93	
Treatment for osteoporosis or low bone density last month	No(ref.)			<0.0001
	Yes	2.87	1.82-4.51	
Bone broken in last 5 years	No(ref.)			0.0008
	Yes	1.73	1.26-2.39	
History of high blood cholesterol	No(ref.)			0.0015
	Yes	1.57	1.19-2.08	
History of anxiety/depression	No(ref.)			<0.0001
	Yes	2.04	1.52-2.75	
Self-rated health	Excellent(ref.)			0.0467
	Very good	1.44	0.89-2.33	
	Good	1.43	0.86-2.39	
	Fair	1.65	0.90-3.04	
	Poor	3.26	1.50-7.12	

Changes to testosterone prescribing

- As of March 2015 Pharmaceutical Benefits Scheme subsidised prescribing restricted by
  - requiring treatment to be under the guidance of an endocrinologist, urologist or specialist in sexual health medicine
  - requiring two separate blood samples on different mornings to confirm androgen levels
  - excluding treatment of androgen deficiency due to age, obesity, cardiovascular diseases, infertility or drugs.

Testosterone prescribing in Australia 1992 to 2016



Conclusion

- Recent restrictions placed on subsidised prescribing of testosterone has reduced prescribing of testosterone
- Prescribing of testosterone remains high
- Results from the 45 and Up study suggest that prescribing may be occurring outside indications for use
- Whether restrictions on subsidised prescribing has had an impact on private prescriptions is not known