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Evidence of overtesting for vitamin D **DEN** in Australia: an analysis of 4.5 years of Medicare Benefits Schedule (MBS) data

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ABSTRACT

Objective: To comprehensively examine pathology test utilisation of 25-hydroxyvitamin D (25(OH)D) testing in each state of Australia to determine the cost impact and value and to add evidence to enable the development of vitamin D testing guidelines.

Design: Longitudinal analysis of all 25(OH)D pathology tests in Australia.

Setting: Primary and Tertiary Care.

Measurements: The frequency of 25(OH)D testing between 1 April 2006 and 30 October 2010 coded for each individual by provider, state and month between 2006 and 2010. Rate of tests per 100 000 individuals and benefit for 25(OH)D, full blood count (FBC) and bone densitometry by state and quarter between 2000

Results: 4.5 million tests were performed between 1 April 2006 and 30 October 2010, 42.9% of individuals had more than one test with some individuals having up to 79 tests in that period. Of these tests, 80% were ordered by general practitioners and 20% by specialists. The rate of 25(OH)D testing increased 94-fold from 2000 to 2010. Rate varied by state whereby the most southern state represented the highest increase and northern state the lowest increase. In contrast, the rate of a universal pathology test such as FBC remained relatively stable increasing 2.5-fold. Of concern, a 0.5-fold (50%) increase in bone densitometry was seen.

Conclusions: The marked variation in the frequency of testing for vitamin D deficiency indicates that large sums of potentially unnecessary funds are being expended. The rate of 25(OH)D testing increased exponentially at an unsustainable rate. Consequences of such findings are widespread in terms of cost and effectiveness. Further research is required to determine the drivers and cost benefit of such expenditure. Our data indicate that adoption of specific guidelines may improve efficiency and effectiveness of 25(OH)D testing.

INTRODUCTION

Concerns are increasingly being raised about the potential of medicine to harm the healthy. Reports suggest that there is an increase in overscreening and overdiagnosis

ARTICLE SUMMARY

Article focus

- Overscreening and overdiagnosis for conditions that would never cause symptoms have the potential to lead to unnecessary labelling and overtreatment.
- A dramatic increase in 25-hydroxyvitamin D testing is apparent in many developed nations.

Key messages

- There is a dramatic increase in testing across each quarter of the year and for individuals having up to four tests.
- Many tests are potentially being ordered unnecessarily.
- A review of testing guidelines is warranted.

Strengths and limitations of this study

- Strengths of this study include the ability to include all vitamin D tests and diagnostic test for breast cancer in Australia over a 4.5-year period.
- Limitations include the inability to obtain information on the precise reason for vitamin D testing in individuals.

for conditions that would never cause symptoms, resulting in unnecessary labelling and overtreatment of healthy individuals. 1

Testing and diagnosis for 25-hydroxyvitamin D deficiency (25(OH)D) are good examples. Testing and diagnosis has reached levels that raise serious questions as to the true prevalence of the disorder, the accuracy of testing methods, the cost benefit of diagnosis and treatment and whether this is being translated into improved health outcomes. In accordance with other Australian studies,² we recently reported that the prevalence 25 (OH)D deficiency in an Australian population was greater than expected, ranging from 33% in summer months to 58% in late winter and spring months.3 In a separate study, we reported a massive increase in the frequency of testing for serum 25(OH)D levels over an 11-year period in Australia.4 The rate of testing had increased from 40.6 (tests/

100 000 people) in the year 2000 to 3472.2 (tests/100 000 people) in 2011. As a result, the cost of testing for 25 (OH)D in Australia had increased from \$1.0M in the year 2000 to \$95.6M in the year 2010, or on average 59% each year.⁴ Small reports from the USA and Canada have also indicated rising test trends and costs for 25(OH)D testing.⁵ Similarly, the UK has seen a sixfold increase in 25(OH)D tests between 2007 and 2010.⁶

The consequences of these findings are widespread in terms of better quantifying the magnitude of risk of 25 (OH)D deficiency for a given population as well as gaining a better understanding as to the best way of testing for the disorder to avoid unnecessary cost and the potential for overdiagnosis and overtesting. The aim of this study was to examine the pattern of 25(OH)D testing in individual patients over a 4.5-year period in Australia so as to inform the development of testing guidelines.

METHODS

Medicare is Australia's publically funded universal health insurance scheme. A comprehensive range of services, diagnostic procedures and tests is itemised as the Medicare Benefits Schedule (MBS). Every public or private patient in the ambulatory setting receives a reimbursement via Medicare for services provided by General Practitioners (GPs) or specialists. Analysis of MBS data provides information on patterns and trends in healthcare utilisation.

The MBS was analysed by using specific item numbers for 25(OH)D testing, bone densitometry (dual energy x-ray absorptiometry) and a commonly requested reference test, full blood count (FBC). The latter was used as a control for pathology test utilisation as it is unlikely to have been influenced by topical health trends. For individuals who had one to five tests, we used analysis of variance adjusting for multiple comparisons using Bonferroni post hoc tests to determine whether there was a significant difference in the mean number of individuals being tested each year by quarter (not including duplicate tests) for each test frequency. All analyses were performed using SPSS V.19.0.1 (July 2010).

Medicare provider data from 2006 to 2010

To test the hypothesis that overtesting could explain the increased number of tests, we investigated the frequency of 25(OH)D testing (item number 66 608), 25(OH)D test data between 1 April 2006 and 30 October 2010. These data were obtained from the Information Strategy & Delivery Section of Medicare Australia by personal request. Each individual was coded then de-identified by Medicare prior to the release of data. Date of test, provider (GP or Specialist) and location of test by state or territory: New South Wales (NSW), Victoria (VIC), Queensland (QLD), South Australia (SA); Western Australia (WA), Tasmania (TAS), Northern Territory (NT) was provided for each participant. Ethics approval was not required as Medicare data are freely available to the general public.

RESULTS Frequency of testing

Approximately 4.5 million 25(OH)D tests were conducted in 2.4 million individuals between 1 April 2006 and 30 October 2010. Of the individuals tested, 57.1% of individual cases had one test in that period and 42.9% of cases had subsequent testing (table 1A). The frequency of tests for each individual varied between 1 and 79 in that period (table 1B). Of the total number of tests, 54% of tests were initial tests and the remaining 46% of tests were subsequent tests, 25% of which were for the second test, 11% the third test and 6% the forth test. The remaining 6% of 25(OH)D tests were for between 5 and 79 tests in that period. Although we were able to distinguish between GP versus specialist, the data were not specific enough to determine if the same provider was performing each test.

The number of tests for each quarter increased each year from 2006 to 2010 for individuals who had between one and four tests whereby the most rapid increase was for individuals who had one test. When investigated according to quarter, the number of individuals having 2–4 tests also increased from 2006 to 2010 for all quarters. However, the highest number of tests was consistently performed in the second quarter of each year

Table 1 Number of individuals according to the frequency of tests for each individual between 2006 and 2010

	Number	Per cent
(A) Number of cases		
Cases (no repeated test)	1365369	57.1
Case (with repeated	1026483	42.9
testing)		
Total cases	2391852	100
Frequency of testing per	Number of	Per
individual	individuals	cent
(B) Ereguency of reposted to		
(B) Frequency of repeated te		54
1 2	2391852 1026483	23
3	496225	23 11
4	251306	6
5	132173	3
6	71534	2
7	39857	1
8	22717	1
9	13165	0
10	7790	0
11–20	13007	0
21–30	255	0
31–40	219	0
41–50	77	0
51–60	28	0
61–70	20	0
71–80	11	0
Total duplicate tests	4466719	100
Total duplicate tests	1700/13	100

whereby the number of individuals who had one test exceeded 40 000 (figure 1A). Interestingly, the number of individuals who had one test in the third quarter was the lowest, yet the number of individuals who had two tests in that quarter was the highest, resembling the second quarter. When plotted as a whole, the seasonal periodicity showed that the highest number of tests was consistently performed in the third quarter (June—August) and lowest number in the fourth quarter (September–November), which are in the winter and spring months, respectively (figure 1B).

For the first quarter of each year, the proportion of individuals who had two tests increased approximately linearly from 2% in 2006 to 9% in 2010 (table 2). Similarly, for individuals tested in the second quarter, who had two tests, the proportion increased linearly from 9% to 22%; those tested in the third quarter increased from 20% to 39%; while those tested in the fourth quarter remained relatively stable from 2006 to 2010. For individuals who had three tests, the proportion was the highest in each year for the third quarter, increasing from 3% in 2006 to 8% in 2009.

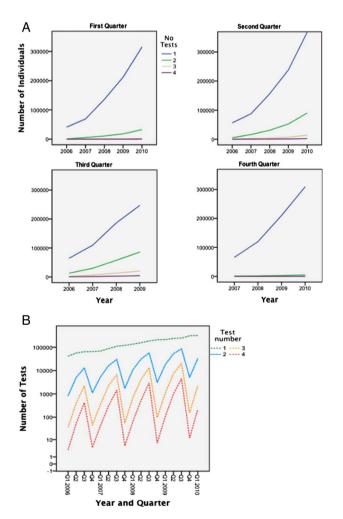


Figure 1 Mean number of individuals who had one test each by quarter and year.

Provider

The proportion of 25(OH)D tests ordered by GPs between 2006 and 2010 varied from 71% to 85% by state whereas specialists ordered between 15% and 27% of tests (figure 2A). The proportion of specialists who ordered tests relative to GPs was highest in the more northerly Australian states and territories (mean 24.25%; QLD, NT, NSW and WA) declining to whereas the proportion of specialists who ordered tests in the southern states and territories decreased to less than 20% (mean 17.25%; ACT, SA, VIC, TAS; figure 2A). The number of tests ordered per quarter between Q2, 2006 and Q3, 2010 by GPs increased approximately linearly by 10.5-fold, whereas the number of tests ordered by specialists increased 5.6-fold (figure 2B).

Rise in testing over the past decade

The national rate of services for 25(OH)D tests has been growing exponentially each year 37/100 000 individuals in 2000–3648/100 000 individuals in 2011 (table 2). In comparison, the rate for a widespread routine pathology test such as a FBC, increased approximately 2.5-fold (3057–10 780/100 000) and testing for bone health, using bone densitometry approximately 0.5-fold (50%) from 60 to 91/100 000 population; table 3.

When investigating the relative increase in rate by states and territories, the rate of testing varied, whereby the biggest increase in testing rate occurred in the most southern state of TAS (424-fold; table 3). Among other southern states, the rate of testing increased 196-fold in SA, whereas in VIC, also at similar latitude, the rate increased only 79-fold, although baseline values were lower in VIC and TAS. Of interest, the relative increase in the rate of testing in other states varied between 32 (ACT) and 81 (NT).

DISCUSSION

The primary source of 25(OH)D for the majority of individuals is exposure of the skin to ultraviolet B radiation in the wavelength 290–315 nm. A serum test for 25(OH)D is the most accurate marker for assessing vitamin D status. Although there is contention as to the accuracy of various assays of 25(OH)D, these assays have become widely available to primary and specialised health practitioners. This improved access to testing alone has led to an increase in testing and subsequently, increased detection of vitamin D deficiency (25(OH)D <50 nmol/L). Hence, there has been an increasing number of studies which have been published showing a higher than expected prevalence of 25(OH)D deficiency.

The common definition of vitamin D deficiency is a serum 25(OH)D concentration less than 50 nmol/L, ¹² where the risk of adverse bone effects is well established. ¹³ A growing body of research suggests that 25(OH)D deficiency may also be involved in the development of numerous chronic conditions including cancer, ¹⁴ autoimmune

Table 2 Proportion of individuals having two, three or four tests number of initial tests for each year and quarter in comparison to individuals who had one test

Year and quarter (%)																	
	2006				2007				2008				2009				2010
Number of tests	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1
2	2	9	20	2	8	19	27	1	8	20	31	1	9	22	35	2	10
3	0	1	3	0	1	3	6	0	1	3	7	0	1	3	8	0	1
4	0	0	1	0	0	0	1	0	0	0	2	0	0	0	2	0	0

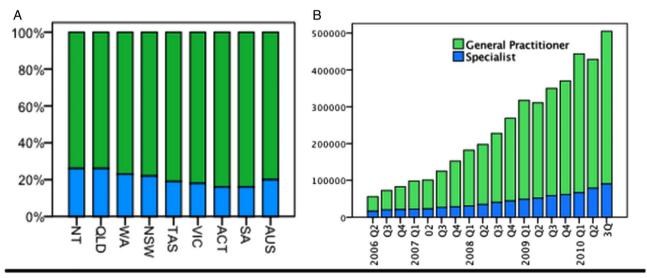
disease, 15 cardiovascular disease 16 17 and diabetes, 18 as well as overall mortality¹⁹ and adverse pregnancy outcomes, ²⁰ other than its role in maintaining adequate bone density. However, most of these findings are from observational studies, for which the evidence is considered inadequate in comparison to randomised controlled trials, and therefore have not been formally accepted by review bodies. Conclusions from a 2011 consensus conference aimed at defining the term 'evidence-based nutrition,' suggests that when examining the effect of nutritional constituents on health outcomes, the totality of evidence be taken into account and it should be subject to it's own nutritional methodologies, as opposed to randomised trials which are required for pharmaceutical drugs.²¹ Nevertheless, because of the new disease associations of 25 (OH)D deficiency, some have proposed raising the diagnostic threshold for 25(OH)D sufficiency to a level greater than 75 nmol/L.

The present study demonstrates that there has been an unsustainable growth in 25(OH)D testing across Australia over the last 11 years which reflects other nations. The consequences of our findings are widespread in terms of unnecessary cost and potential overdiagnosis.

Improved access to health services is unlikely to explain the rise in 25(OH)D testing as a testing for a common pathology test remained stable. It is more likely that the dramatic increase seen is a consequence of preventative testing linked to increased awareness of the health benefits of achieving sufficient 25(OH)D status. The greater rise in the rate of testing in states such as TAS suggests that awareness of the risk and implications of 25(OH)D deficiency is higher in these states as a consequence of TAS's high latitude relative to other Australian states and territories. The hypothesis that community awareness of the risk of 25(OH)D deficiency is driving the rate of 25(OH)D testing in should be formally evaluated.

As expected, due to the relatively higher proportion of GPs in comparison to specialists, a higher proportion of tests were conducted by GPs (figure 2). The over-representation of tests in NSW and VIC is likely to be due to the larger proportion of physicians practicing in these states as well as their higher latitude relative to other states.

Is the amount of money spent on 25(OH)D testing value for money? In order to answer this question, a better understanding of the drivers of 25(OH)D testing as well as



Tasmania, VIC: Victoria, ACT: Australian Capital Territory, SA: South Australia, AUS: Australia; Q1, Jan-Mar; Q2-Apr-Jun; Q3-Jul-Sept; Q4-Oct-Dec

Figure 2 Vitamin D testing by provider between quarter 2, 2006 and quarter 3, 2010.

Table 3 Rate of services and relative increase in rate for 25-hydroxyvitamin D tests subsidised by Medicare between 2000 and 2011

Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
(A) Vitamin D services/100 000 by state												
NSW	58	120	120	157	219	294	544	967	1766	2684	3735	4233
VIC	69	144	144	200	345	480	891	1632	2804	4070	5195	5530
QLD	23	44	44	51	74	97	174	296	581	956	1435	1770
SA	19	84	84	143	224	321	521	871	1624	2383	3503	3769
WA	66	153	153	194	241	294	462	672	1082	1799	2702	3016
TAS	10	34	34	48	129	163	279	488	1048	2216	3576	4058
ACT	160	277	277	407	551	842	1446	2317	3178	4155	4798	5316
NT	18	26	26	49	51	79	115	175	329	734	1226	1520
Australia	37	59	80	109	171	251	397	730	1348	2128	3003	3468
FBC	3057	8459	8735	8782	9044	9517	9939	10 212	10 382	10 480	10 496	10 781
Bone densitometry	60	72	84	83	86	101	100	99	91	89	89	91
(B) Relative increase in	n service	es since	2000									
NSW	0.0	1.1	1.1	1.7	2.8	4.1	8.4	15.7	29.5	45.3	63.4	72.0
VIC	0.0	1.1	1.1	1.9	4.0	6.0	11.9	22.7	39.7	58.0	74.3	79.2
QLD	0.0	0.9	0.9	1.2	2.2	3.2	6.6	12.0	24.4	40.8	61.7	76.4
SA	0.0	3.4	3.4	6.5	10.7	15.8	26.3	44.6	84.0	123.7	182.3	196.2
WA	0.0	1.3	1.3	2.0	2.7	3.5	6.0	9.2	15.4	26.3	40.0	44.8
TAS	0.0	2.6	2.6	4.1	12.5	16.1	28.3	50.1	108.8	231.0	373.5	423.9
ACT	0.0	0.7	0.7	1.5	2.4	4.3	8.0	13.5	18.8	24.9	28.9	32.2
NT	0.0	0.4	0.4	1.7	1.8	3.3	5.3	8.5	16.9	38.8	65.4	81.4
Australia	0.0	0.6	1.2	2.0	3.7	5.9	9.9	19.0	35.9	57.3	81.3	94.0
FBC	0.0	1.8	1.9	1.9	2.0	2.1	2.3	2.3	2.4	2.4	2.4	2.5
Bone densitometry	0.0	0.2	0.4	0.4	0.4	0.7	0.7	0.6	0.5	0.5	0.5	0.5

FBC, full blood count; NSW, New South Wales; NT, Northern Territory; QLD, Queensland; SA, South Australia; TAS, Tasmania; VIC, Victoria; WA, Western Australia.

what the optimal level of 25(OH)D is, is necessary. Drivers that may be relevant to the increase in 25(OH)D testing include the shifting threshold for adequate 25(OH)D levels, incidental diagnosis, failure to recognise normal fluctuations and poor timing of testing. It has also been reported that industries that benefit from expanded markets or physicians wanting to increase their patient pool are major influencers on the rate of testing. On the other hand, the increased rate of testing suggests that there may be value as a result of a greater awareness of the prevalence of 25(OH)D deficiency.

Further studies are required to determine whether this increased testing translates into improved 25(OH)D status of the population and subsequent health outcomes. A worrying trend, however, is that despite the magnitude of the rise in 25(OH)D testing this did not translate into increased testing for physiological endpoints associated with 25(OH)D deficiency, such as osteoporosis. 23 24 over the long term. 25

Our data showing marked variation in the frequency of testing in individuals further support calls for the adoption of more specific 25(OH)D testing guidelines internationally and in Australia. Implementation of clinical guidelines has been shown to improve the quality of healthcare by reducing morbidity, mortality and by increasing cost-effectiveness. ²⁶ ²⁷ A recent position statement advises against retesting before 3 months because it may take 2–5 months for serum levels of 25(OH)D to plateau. ²⁸

Vitamin D supplementation has been shown to increase 25(OH)D levels by approximately 17 nmol/L for each 1000 IU each day, reaching a plateau around 8 weeks.²⁹

Simply advising against routine screening, as is the policy in Australia, is evidently inadequate in preventing excess testing. To illustrate by example, imposing guidelines to limit testing to three per annum: the first test to establish the diagnosis, the second to be performed 3 months after supplementation, and the third test 6 months after supplementation, to ensure that appropriate 25(OH)D concentrations are being maintained. If this approach was adopted, based on the current data, 552 509 tests would have not been undertaken at a saving of more than \$20 million over the 4.5-year period. Still, others question the necessity of testing at all, and suggest that supplementation without testing in high-risk individuals is safe and effective. 30 This is also reflected in the endocrine society's recommendations to supplement the general population with 1000–2000 IU 25(OH)D.¹² Although, serum 25(OH)D has been shown to vary considerably among individuals following vitamin D supplementation, whereby one study has shown that 6100 IU vitamin D supplementation would be required to bring 97.5% of the population up to a serum 25(OH)D level of 74 nmol/L without evidence of toxicity.³¹

Supplementation without 25(OH)D testing is linked to varying viewpoints; for instance, it has been postulated that blanket supplementation would result in substantial

reduction in global healthcare costs,^{32–34} whereas others have shown that 25(OH)D deficiency, combined with lack of monitoring, predicted increased inpatient healthcare costs.³⁵

CONCLUSION

This study demonstrates an unsustainable rate of increase in 25(OH)D testing which is likely to reflect a growing awareness of the consequences of 25(OH)D deficiency on human health. However, our study also indicates that the lack of guidelines for testing leads to inappropriate testing.

At present, there is no agreement as to the appropriate timing and frequency of testing for the diagnosis of 25 (OH)D deficiency. Current recommendations are to test individuals at high risk of deficiency such as the elderly or dark skinned individuals,⁸ although routine testing is currently not recommended by the Australian Bone and Mineral Society,³⁶ or the American Endocrine Society. Additionally, repeated testing 3 months after a loading dose of 25(OH)D supplementation has been recommended^{37 38}; however, there are no formal guidelines for subsequent monitoring of adequacy of replacement therapy for 25(OH)D deficiency in Australia or elsewhere.

Further research is required to better determine the drivers of 25(OH)D testing and cost benefit of such expenditure, although our data indicate that the adoption of specific guidelines are warranted to improve the efficiency of 25(OH)D testing. Such guidelines would necessarily specify criteria for testing, such as diagnosis of 25 (OH)D deficiency disease or other indication of likely having low 25(OH)D levels, including many types of cancer, cardiovascular disease, diabetes mellitus, dental caries, erectile dysfunction, obesity, osteoporosis, periodontal disease, respiratory infections, pregnant women and those admitted to the hospital for any reason. 15 As an alternative, current Australian vitamin D intake recommendations, which range from 200 to 800 IU, 28 39 could be increased in order to increase the number of people with serum 25(OH)D concentrations aimed at optimal health.

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Contributors KB and SB were intimately associated with generating the research concept resulting in this publication. KB was primarily responsible for researching the literature context as presented in the introduction. KB was responsible for data extraction and analysis. KB and SB had full access to the data and were responsible for interpreting and presenting the results. SB contributed to preparing the publication manuscript by generating the first draft and KB by coordinating and editing further contributions and comments. KB and SB were responsible for preparing responses to journal comments and criticisms. All authors have read and approved the final manuscript.

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