Overdiagnosis and osteoporosis

A personal story, or perhaps a polemic, October 2015

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Summary

A BHMA trustee tells of his own encounter with over-diagnosis. He raises the question of risk versus benefit and the vexed question of NNT – 'the number needed to treat' – statistically how many people would have to be treated in order to prevent a single severe outcome. Anyone thinking of embarking on a lifelong drug regime whether for high cholesterol, raised blood pressure or in this case 'osteoporosis' should ask their doctor about NNT and, crucially, whether the drug carries significant risks of severe adverse effects. The author having done so, rejected medication in favour of lifestyle changes which appear to have been highly effective.

I have been interested in alternative approaches to drug-based 'treatments' since being prescribed tranquillisers for random panic attacks in my teens in the 60s. My instinct then told me that this was not treating the cause(s) of my condition; this was verified some five years later when I was one of the first people in the country to be officially diagnosed with hypoglycaemia. A week after the six-hour blood sugar test I had changed my diet accordingly and that was the last time I needed help from the medical profession for my 'symptoms'. Medical understanding has moved on since then, and the internet is a powerful source of patient information, but my instinct remains to use drugs only as a last resort. I have been a layperson trustee of the BHMA for the past few years as it remains the only organisation committed to promoting a person-centred rather than a symptom-centred approach to 'illness'.

> *Given that bisphosphonates can cause severe adverse effects including fractures, which they are meant to prevent, it is urgent that the overall benefits and harms of long-term treatment be clarified. The available evidence suggests that the benefit-harm balance may be unfavourable for their use in osteoporosis.*
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> Drug and Therapeutics Bulletin

I am a 'healthy' 68-year-old man who four years ago was diagnosed with osteoporosis in the spine and osteopenia in the hip following a minor accident at home. I had no obvious predispositions, other than a genetic link on the female side with my sister, aunt and grandmother, although in the preceding four years I had cracked a rib and broken toes twice. Following my DEXA scan I was alarmed to be told I had an advanced medical 'condition' and was urgently in need of drugs (I was recommended 18 months of parathyroid hormone – PTH – followed by continuous bisphosphonates). I quickly accepted that my bones were less dense, strong and healthy than was ideal, but what I couldn't accept were the various drug treatments prescribed – for reasons that I will explain later. What I have since learned is that I am far from alone in suspecting that bisphosphonates might do more harm than good, as I subsequently discovered when I saw a highly sceptical critique of one influential guideline:

> *Poole and Compston's review (2011) overemphasises the benefits of bisphosphonate and downplays the serious harms. Given the small magnitude of benefit and the potential that this estimate exaggerates true effects due to incomplete reporting, this judgment call is at odds with that of organizations without financial links to these drugs' manufacturers*
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> (Musini 2012)

Beating osteoporosis without drugs?

To keep you reading I will give you the punchline now – in the first two years without any drugs I increased my

spinal bone density by 7% (measured on the same machine, before you ask). The individual machine accuracy is rated around 1–2% between scans. I am told that this level of improvement at my age is unusual, noteworthy even. In the subsequent two years I held this position for my spine, and meanwhile the osteopenia I had been diagnosed with in my hips slipped back into the 'normal' range when adjusted for my age, gender, race, weight etc. (I had maintained density while those around me, ageing at the same rate, had lost density. The statistics had made me well again…).

Even a quick trawl on the internet revealed that osteoporosis is very much a statistically defined 'disease', related more to age (and the female menopause) than any pathogenic presences. For those who don't know, a standard deviation of -1.0 in bone density is defined as osteopenia and one of -2.5 as osteoporosis. The normal curve is chosen as an average of 'healthy' 25-year-olds. Osteoporosis and its little sibling or precursor osteopenia, is pretty much defined as an increased risk of bone fracture as a result of this lower bone density. You might think this a very odd way to define a disease – that it is a likelihood of suffering from a future bodily dysfunction or accident, and perhaps an even odder basis for prescribing drugs. But of course on reflection this is precisely why moderately raised blood pressure provokes so much medical attention, for though it's usually symptomless it points to a greater risk of heart attacks and stroke.

An invented disease?

So in a sense these are not diseases as such, but rather bodily states that signpost increased risk of disease. To push my point further, ought doctors to find some drugs for those statistically very tall as they must have a greater risk of damaging their heads in normally designed environments? Or drugs for those with statistically slower reflexes since they are surely bound to suffer from more traffic accidents? In case drug companies might get to read this I will defer from making further suggestions and leave it to the reader's imagination….

As a reasonably well-educated layperson, I began to wonder whether all diseases are defined statistically? And I am perhaps just being too naive…? There do seem to be 'normative ranges' for pretty much any body-related measurement. For instance if my blood test results are to be believed, there is a wide range which appears to be 'OK'. So some kind of standard deviation curve containing 'normal' and 'sick' will apply throughout medicine. But must that imply the need for treatment, particularly drug treatment wherever someone's measurements overstep the mark? Anyway, if there is a measurable factor, who decides the cut-off point? And, if a person's measurement is at the boundary end of a statistical curve, shouldn't this be a signal – before reaching for the tablets – to aim at nudging them back into the normal range? In the circumstances, I was the one who had to call for a timeout. But surely this obvious first step back to 'normality' shouldn't depend on the occasional inquisitive, perhaps stubborn layperson such as myself.

What does 'normal' mean?

When someone's test results lie outside the standard parameters there are surely some simple questions to ask first, particularly does it matter? If a clinician can be sure – on the basis of well established criteria – that an abnormal test result definitely increases some specific risk to health, there is obviously a discussion to be had about whether 'something needs to be done'. The first question to ask is how many people would need to be treated in order to prevent one major disabling incident? This at least would lay down some certainty about a treatment's likely effectiveness and efficiency. But on the other hand this has to be set against the possibility that the treatment itself might cause impairment, suffering or even death. But it's my impression that despite all the rhetoric about self-management not only are these risk–benefits too seldom discussed, also that across the board too little is known about the potential for lifestyle changes to improve the prognosis of many long term conditions. This strikes me as very odd: lifestyle changes are cheap, and should always be the first tactic suggested, given the current and predicted pressures on health budgets.

Lifestyle changes may not work of course: perhaps a condition is unresponsive to them, or the particular risk profile has been spotted too late, or the person at risk will not or cannot make the, perhaps rigorous, changes required. Then drugs might have a role. Anyway, 'improvements' from lifestyle changes are likely to be very slow. After all it may have taken many years for a person to edge their way outside the statistical curve. Or perhaps some of us were always at the biometric margins because that's the way are constituted: just as some folk are at the taller end of the spectrum, some are going to be at the extreme end of a bone density curve.

Which brings me neatly back to a discussion on suitable drugs to treat osteoporosis; but perhaps not just yet, for two reasons. Firstly, who decided on this -1.0 and the -2.5? It was actually WHO, the World Health Organization, that decided to set a world standard, (and perhaps this serves to help comparative research happen). But do these standard criteria truly signify whether someone with a statistically -1.0 less dense bone has a less strong or healthy bone than one at 0.0. As far as I can discover, the answer is no: we can now easily measure bone density, but it is not at all easy to measure bone strength or health.

Problems with bisphosphonates

I am sure you are impatient to move past this semantic-philosophical discussion of whether osteoporosis is a disease or not, or how many millions of people we should treat or not, and get to the actual wonder drugs prescribed. After all if we can improve people's bone

density with them and reduce their fracture risk then why am I being such a bore? Well, first off because the drugs prescribed – invariably bisphosphonates of some kind – don't actually increase bone density. They just stop further bone loss by inhibiting the natural mechanism for dissolving bone back into the blood, which is normally balanced by new bone being built from constituents in the blood (I am keeping this simple rather than technical).

So if you're on bisphosphonates your bones get older and inevitably less healthy overall, but that shouldn't matter because at least they don't get less calcium-dense. And the real benefit of using the drugs is of course that they reduce the statistical risk of future fracture, which is where we started with all the definitions. But wait for it, there is a snag here too – the drugs do not in fact seem to decrease the risk of future fractures – some recent studies even indicate an increased risk. This has not surprised me as the drugs anyway seem a poor solution to someone like me who is interested in maintaining or achieving *healthy* bone. A fairly recent review of the evidence in this year's *BMJ* now tells us conclusively that after 15 years of these drugs being used by millions of people (mostly post-menopausal women), they actually don't prevent fractures. (Jarvinen *et al* 2015).

> The bisphosphonates do appear to reduce fractures among women with very low bone mineral density (BMD) and those who have had previous fractures, and should be considered. However in those without very low BMD or fractures no study has demonstrated a true benefit (the NNT, 2015).

For the record, I should state that my own specialist recommended that, as my spinal bone density was so low, I should take a parathyroid hormone that was 'guaranteed' to increase my bone density by some 5% over the two years allowed. This is a very expensive treatment not available on the NHS. When I questioned 'why only two years and what happens then' he said it was not proven to be safe over a longer term(!) and at that point I would need to take the bisphosphonates anyway. As I wanted my bones to stay in a healthy and natural exchange with my blood, I declined his advice.

What are the alternatives?

I do not feel this is the right article, nor probably am I the best qualified person, to go into serious critiques of the drugs or alternative methods of treatment or the research that underpin them both. But as a gesture in that direction, the regime I independently developed is very close to one described recently in the *Ageing Well* e-book on www.wddty.com/health-books.html. I would also recommend following two web resources – first, Susan Brown on www.betterbones.com and her daily betterbones blog, with the small proviso that there are a lot of products to buy… She subscribes to the popular alternative view that our modern western diets tend to create too much blood acidity, and that if too little dietary calcium is available to rebalance this then the body will pull calcium from the bone to maintain optimum pH values. I am unsure that this theory is entirely evidence-based, but it remains an attractive explanation for the *established* fact that diets rich in dairy and calcium statistically correlate worldwide with *increased* rates of osteoporosis (the argument being that all that dairy calcium is needed first to neutralise the acidifying effects of all the protein in the dairy…) Second, Vivien Goldschmidt on www.saveourbones.com has a wealth of material and also a daily blog that is a great reminder to keep focused. She has an interesting new programme and book called *Densercise*; a great exercise regime for increasing bone density naturally, in just 15 minutes a day without apparatus – I have not tried this yet, but generally rate her advice very highly. Both women have a 'healthy' scepticism about drug treatments, and encouraging advice on how to maintain self-sufficiency with this statistical 'condition'.

On the diet side, I chose to take an absorbable supplement of calcium, vitamin D, vitamin K, Boron etc – the NHS prescription tablets are not well absorbed by the body, and I declined them. I cut down on dairy products other than live yoghurt, greatly increased my consumption of green leafy vegetables (and seaweeds!), and ate more nuts and seeds and less meat. On the exercise side, I walked most days for at least 30 minutes (I already swam and cycled moderately often, but these do not really build bone as they are not weight-bearing). I also used a small exercise trampoline and a vibration plate on a daily basis – self-prescribing additional gravity. Astronauts all lose bone density in space and these are part of what they have to do to regain bone density when back on earth. A trampoline should probably be used with caution by those who are not confident of their level of fitness and balance but to my knowledge the vibration plate is safe for all levels of physical ability.

On the research side, for those seeking 'some facts' rather than my observations, pages 204–11 of the fascinating book *China Study* by Colin and Thomas Campbell (Benbella Books, Texas 2006) quotes plenty, and the two web authors Vivien Goldshmidt and Susan Brown previously mentioned do so too and always critique relevant new research from all around the world on their blogs.

On the personal side, DEXA scans and blood tests are probably useful aids; I have mentioned the limitations of DEXA results, and according to my reading blood tests are probably only useful to identify those people with specific underlying biophysical conditions that lead to the low bone density. Measuring blood calcium levels for example is not much help, as the body needs the calcium levels kept at the correct level in the blood far more than it needs it in the bones.

My own strategy for tackling the more general problem of over-diagnosis would not improve profits of some

distant corporation; rather the reverse. First, research your ailment very carefully (check out quick summaries of evidence-based medicine http://www.thennt.com). Second, listen to your doctor carefully. Third, question whether that doctor is interested in understanding your ailment to anything like the degree you are. Fourth, ask your doctor why they believe a drug might shift your risk in the direction of better overall health and well-being, and/or whether that would be the best way to achieve this. And look hard, with or without your doctor, at lifestyle and potential changes using any or all of the technologies and regimes available for diagnosis, diet and exercise etc, including the web resources I have indicated. The extraordinary potential of engaging with self-care (better exercise, relaxation and nutrition) cannot be overstated. The nation's health requires an educated and motivated population, and the support of doctors who encourage both these and maximum patient engagement, rather than a mounting dependency on an increasingly over-stretched NHS.

In summary, I wish you an engaging time considering the more general problems of over-diagnosis and that you will be grappling with the question of what might be done about it. I hope this paper throws some light into some murky corners…

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Osteoporosis causes bones to become weak and brittle â€” so brittle that a fall or even mild stresses such as bending over or coughing can cause a fracture. Osteoporosis-related fractures most commonly occur in the hip, wrist or spine. Bone is living tissue that is constantly being broken down and replaced. Osteoporosis occurs when the creation of new bone doesn't keep up with the loss of old bone. Osteoporosis affects men and women of all races. Osteoporosis, a chronic, progressive disease of multifactorial etiology (see Etiology), is the most common metabolic bone disease in the United States. It has been most frequently recognized in elderly white women, although it does occur in both sexes, all races, and all age groups.Â Practice Essentials. Osteoporosis, in which low bone mass and micro-structural deterioration of bone tissue lead to increased bone fragility, is the most common metabolic bone disease in the United States. To diagnose osteoporosis, doctors will perform physical exams, ask questions about your medical history and symptoms, and test your bone mineral density.Â Osteoporosis is a condition that occurs when a person experiences significant loss of bone density. This causes bones to become more fragile and prone to fracture. The word â€œosteoporosisâ€ means â€œporous bone.â€ The condition commonly affects older adults and can cause height loss over time. What are the steps to an osteoporosis diagnosis?