

Large clinical trials to evaluate risks of testosterone treatment urgently needed

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Physicians do not have sufficient information from clinical trials to understand the risks associated with the prescription of testosterone in older men, according to a Comment in *The Lancet Diabetes & Endocrinology*, written by Professor Stephanie Page, of the University of Washington and Harborview Medical Center, Seattle, USA.

While the benefits of <u>testosterone</u> therapy in younger men with a deficiency of the hormone are well established, testosterone is now widely prescribed to <u>older men</u>, particularly in the USA.

Existing studies have produced conflicting findings over whether the prescription of testosterone is associated with increased cardiovascular risk in older men, and ongoing studies are unlikely to adequately address this question, meaning that even if an appropriately powered trial were to start today, reliable safety data are at least a decade away.

According to Professor Page, "In an era when millions of men are using testosterone every day, support is urgently needed from both the public and medical communities to fund an appropriate clinical study to assess the risks and benefits of testosterone treatment in older men. There is a danger that funding and regulatory agencies will overinterpret the evidence from existing and ongoing observational studies, and conclude that larger and longer <u>clinical trials</u> are unnecessary and unwarranted. This conclusion would do men's health a disservice."

"Testosterone is a billion dollar industry, probably fuelled partly by



direct to consumer advertising and some degree of overprescription," Professor Page adds. "Physicians need to discuss with their patients that we simply do not fully understand the risks associated with testosterone use in older men, and use conservative treatment guidelines – such as those provided by the Endocrine Society – to guide therapeutic decisions."

More information: Paper: <u>www.thelancet.com/journals/lan ...</u> (14)70082-8/abstract

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