

# To NICE and beyond; what's new with GH?

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There have been a number of recent developments and guidelines in paediatric growth hormone (GH) therapy that have left not only patients and parents confused, but also health care professionals! I've been asked if I'd deal with a number of the common questions asked of the CGF regarding GH therapy.

## **NICE: What is it?**

The National Institute for Health and Clinical Excellence (NICE) is a government body set up to ensure that new and existing technologies (including drugs such as GH) used in the NHS are cost effective. As much as possible NICE guidance is based on firm evidence from well run drug trials. This NICE guidance is likely to become increasingly important as funding to the NHS comes under pressure, and also the fact that many new drugs are likely to be very expensive.

## **NICE review of GH in children (TA88)**

The original review of GH in children came out in May 2002, and was planned to be updated in 2005! One of the reasons for the delay was the limited amount of high quality trials of GH in children, as it is considered unethical to 1) give a placebo (dummy drug) by regular injection and 2) use an untreated group of children as a control group, as many indications for GH have been in use for many years and are considered to be beneficial.

Despite these limitations the current review of GH in children (which can be viewed on [www.nice.org.uk](http://www.nice.org.uk)) has advised that:

- 1) All of the current licensed indications for GH therapy in children: GH deficiency, Turner syndrome, Chronic renal insufficiency (CRI), Prader-Willi syndrome (PWS), small for gestational age (SGA) and SHOX deficiency. This is important, as the last 2 licenses had not been granted at the time of the last review in 2002, and this has caused some problems in getting GH prescribed.
- 2) As many units in the UK now offer free patient choice for new patients starting GH therapy, and there is some (limited) data that this might be associated with improved adherence with therapy and short term-growth, NICE has recognised that, and states: "*The choice of product should be made on an individual basis after informed discussion between the responsible clinician and the patient and/or their carer about the advantages and disadvantages of the products available, taking into consideration therapeutic need and the likelihood of adherence to treatment*". NICE also goes on to say: "*If, after that discussion, more than one product is suitable, the least costly product should be chosen.*" Although many people are very happy with the principle of patient choice the last sentence is leading to different interpretation by different people!

## **What's the difference between the different GH products, and what's a biosimilar?**

Basically all growth hormones (currently seven in the UK) produced by the different manufacturers are (probably) the same, and you could argue it's like deciding to fill your car with only one brand of petrol! All types of GH now used are fully synthetic versions of human GH; the main difference between is in the device used to administer it, and the cost. The cost of bringing a new drug to the market is often several hundred million pounds, and as a result new drugs have an exclusive patent that means that they can't be copied (as biosimilars) until the patent has lapsed. Although people are confused with biosimilar drugs we all use them regularly; if you go to your local supermarket you'll see drugs like Brufen which is widely advertised, and is well known, alongside their own biosimilar brand Ibuprofen, which is often a fraction of the price, and has an identical effect. Although GH is a much more complex drug, and there are some arguments with some drugs as to whether biosimilar is truly bioidentical, the principle is the same.

Although often biosimilar drugs are very much cheaper than other equivalent drugs this is currently not the case with GH, although there is a more than 20% difference between the most expensive and cheapest GH. With the current recession the purchasers (usually the Primary Care Trusts (PCTs)) are having their budgets tightly squeezed over the next few years, and they will be inevitably looking to make savings on drug costs to avoid having to lay off staff. Since a 20% saving with GH could potentially be over £10 million each year, a number of PCTs are considering only offering the cheaper brands, either for new patients but potentially also to change existing patients to cheaper brands: this is something that occurs commonly in other countries such as the USA. What is also unclear if this will produce a price war which could ultimately drive some manufacturers out of the market, or mean that in order to cut prices that additional services such as nursing support and home nursing might no longer be provided.

## **NICE, postcode prescribing and treating off-licence (including SGA)**

One of the reasons for setting up NICE was to put an end to postcode prescribing, whereby where you lived in the country decided what treatment you got. In many ways the NICE GH review is good news as it sets down the evidence

base for treatment, and in addition it has ratified all of the licenses, but whilst NICE turning down a treatment usually means that you won't get it, having NICE approval doesn't necessarily mean that you will! Ultimately the decision as to what treatments are offered needs to be made locally, and as budgets get tighter then the dreaded "R" word: "rationing" of scarce resources is going to be much more explicit to provide best value for money.

Some postcode prescribing is therefore inevitable as different PCTs set different priorities, and the SGA licence is an area where we've previously seen a lot of variation. We know that although they shouldn't have, that some PCTs wouldn't previously prescribe GH under the SGA licence, as it didn't have NICE approval, even though the government said that not having NICE approval should not be used as a reason for not prescribing a treatment. Even with NICE approval it appears that some PCTs are still not agreeing to prescribe GH even where the patient fulfils the license.

Unlike the USA, where the SGA license is from 2 years of age, the European license is explicit (which NICE has confirmed) that treatment should only be from 4 years of age when the other strict criteria (low birthweight/length, lack of catch up growth and short stature both compared to other children and also their own parents) are met. Although NICE does not preclude patients being treated "off-licence" (eg. SGA patients from 2 years of age) it is likely that this will be increasingly difficult over the coming years without very good evidence to back it up.

I hope that this helps to explain some of your queries. If you're still confused; don't worry, you're not the only one!