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BMJ INVESTIGATION

Banking baby teeth: companies may be misleading parents with "outrageous claims"

Experts are concerned by claims—including possible future treatments for autism and diabetes—made about the value of banking baby teeth. Emma Wilkinson reports

Emma Wilkinson *freelance journalist*

Parents are spending thousands of pounds to bank stem cells from their children's milk teeth—but the recipient companies' claims about their future medical value are unproved and potentially misleading, an investigation by *The BMJ* has found.

The three UK companies advertising tooth banking services tell parents that milk teeth are a "valuable" source of stem cells, with the ability to repair tissue cells throughout the body. Their claims include that these stem cells are already being used in treatments for autism and diabetes. They also point to current research using stem cells in multiple sclerosis, myocardial infarction, and Parkinson's disease.

But several experts have told *The BMJ* that they are concerned about the claims being made, which risk exploiting parents—with the promise of a treatment for autism deemed particularly outrageous.

The BMJ found that the three companies in the UK (see box 1) offering tooth stem cell banking—BioEden, Future Health Biobank, and Stem Project—all operate through one laboratory. The Advertising Standards Agency (ASA) says it will review concerns we have raised about how the service is promoted on their websites.

Box 1: Companies offering tooth stem cell banking in the UK

Future Health Biobank https://futurehealthbiobank.com
Has been offering tooth stem cell banking since 2010. In 2019 it acquired BioEden. The laboratory that processes the cells is based in Nottingham.
BioEden https://bioeden.com/uk
Marketed as the first company to offer tooth stem cell banking, it began offering the service in 2008. It is now part of Future Health Biobank but retains separate website and branding.
Stem Protect www.stemprotect.co.uk
An independent company, Stem Protect is owned by a director of Business Waste Ltd. Future Health Biobank handles all the logistics and banking of sample cells.

In response to *The BMJ*, Future Health Biobank says it is looking at how information on its site is presented in order to ensure "readers can clearly distinguish between client experiences and formally published clinical outcomes."

Banking baby teeth

Tooth stem cell banking is also known as dental pulp cell banking. It involves parents collecting and sending lost milk teeth to a laboratory where the dental pulp is "digested" and the cells cultured until "a sufficient number of stem cells are present." They are harvested, counted, and subjected to "viability and sterility" testing, before being cryopreserved (see box 2).

Box 2: Tooth stem cell sample collection and storage (according to Future Health Biobank)

Checks are done that the tooth is healthy, has been collected and transported in accordance with validated procedure, and is suitable for processing.
The dental pulp is digested and the cells are cultured until a sufficient number are present, or maximum time to ensure the naivety of the stem cells present is not lost—whichever is sooner.
The cells are harvested, counted, and viability and sterility testing done before they are cryopreserved in multiple vials, based on the number of viable cells present, ensuring a viable culture can be generated from each vial.
One vial is stored specifically for quality control testing—this involves thawing and culturing the cells and performing flow cytometry to confirm the presence of cell surface markers.
All samples are stored in vapour phase liquid nitrogen. Once cryopreserved, the sample could theoretically be stored indefinitely.

Stem cells were first isolated from teeth in 2000,[1] and less than a decade later companies began to offer tooth stem cell banking. These stem cells are "especially valuable because they are younger and healthier," Future Health Biobank says.

Current research is looking at the use of mesenchymal stem cells (see box 3)—such as found in bone marrow—in anaemia, autism, multiple sclerosis, myocardial infarction, Parkinson's disease, and type 1 diabetes, the companies offering the service explain.

Box 3: What counts as a stem cell?

There is debate among researchers as to the classification of non-embryonic stem cells. Areas of discussion include whether stem cells derived from dental pulp are comparable with those derived from bone marrow. The latter are generally known as mesenchymal stem cells—but that name itself is under scrutiny, with some academics suggesting they should be referred to as "stromal" or "signalling" cells to reflect their more limited capacity than the "stem cell" denomination infers.

Stem Protect also cites cleft palate repair, HIV/AIDS, knee cartilage repair, severe combined

immunodeficiency, and sickle cell disease under a section of its website headed "What treatments are tooth stem cells used for?"

Consumers sign an agreement before being sent a collection kit when their child's tooth becomes wobbly. There is an initial cost of around £1900 (€2189; $2573) and an additional annual storage fee of £95.

Yet several experts tell *The BMJ* it is not clear if parents are able to make a fully informed choice. There is no reliable advice or explanation of the science or the ethical matters around tooth stem cell banking apart from that offered by the companies. There is no public bank for tooth derived stem cells.

Diabetes cure

Jill Shepherd, senior lecturer in stem cell biology at the University of Kent, says there is not enough evidence to suggest that stem cells from teeth should be banked for autologous use. This option has been open to parents for many years, she explains, but it has not attracted the same attention as cord blood banking.[2]

Shepherd points out that companies are selling the "potential" for something that is not yet borne out by the science. "There is a lack of evidence and a paucity of research using dental pulp stem cells to treat patients," she says.

Parents seeking tooth stem cell banking may be grappling with the diagnoses for which companies are promising future therapies, including diabetes and autism.

News late last year that scientists had successfully reversed type 1 diabetes using stem cells in a 25 year old woman caused a flurry of excitement on online forums among parents whose children have the condition.

In the study from China, reported in *Cell*, scientists extracted adipose cells from the patient and reverted them to an unspecialised state, before reprogramming them as pancreatic islet cells and reinjecting them into the patient's abdomen.

Less than three months after the procedure she was producing enough of her own insulin to achieve glycaemic control, which was sustained at a one year follow-up. A lesser reported detail was that she was already on immunosuppressants because of a liver transplant.

Alongside the enthusiastic online sharing of the Chinese research were queries about tooth stem cell banking. Is this something parents should consider as a future source of stem cells for treatment, they asked.

Shepherd explains that the small study used cells derived from fresh tissue, which could be different from the material available to extract from frozen samples. "All this detail matters," she says. "There's no evidence to suggest stem cells stored from a child's milk tooth would ever be needed to treat that child."

"Samples released for treatment"

Future Health Biobank says on its website that it has released 26 tooth stem cell samples for treatment. Examples of the conditions those stem cells were used to treat include autism, type 1 diabetes, and knee cartilage regeneration. All the samples went to private clinics in North America in 2016 and 2017.

The BioEden website says stem cell therapy has been described as the "next frontier" for treating both type 1 and type 2 diabetes. The company states it has "already witnessed the remarkable evidence of these ongoing developments" among its customers.

One 28 year old treated with dental cells has reported "decreased swelling, an improvement in energy levels, and a reduction in their insulin application," the website states. "Another member, who's halfway through their treatment, has had similar results along with improvements in their liver function, and is to begin their second course later this year," it continues.

"The best stem cells are young stem cells," which is why it is "advisable" to bank at the youngest age possible, it adds.

No active human clinical research

Sufyan Hussain is an investigator on the UK arm of a global clinical trial evaluating stem cell therapy, the first of its kind to involve stem cell infusion for type 1 diabetes in the UK. A Medical Research Council funded clinician at King's College London, he also has type 1 diabetes and is concerned about what is being promised. "At present, there isn't a definitive answer regarding the optimal source of stem cells for future diabetes therapies.

"I've had inquiries from people with type 1 diabetes about banking cord blood but, currently, there's insufficient evidence to support or guide this practice. As research progresses and effective stem cell derived treatments become available, we'll gain greater clarity."

He adds that work on dental pulp stem cells is at a very early pre-clinical stage.

"The stem cells being studied in clinical settings are predominantly from either donated embryos or sources readily available from adults. To my knowledge there is currently no active human clinical research using stem cells derived from baby teeth to treat diabetes."

He believes that clear, evidence based information is essential, given the strong interest from people with type 1 diabetes and their families. "This highlights how emotive this matter can be, as parents naturally want the best possible outcomes for their children. While we remain hopeful about future treatments, there is also a risk that companies might exploit these hopes to generate additional revenue."

Diabetes UK shares his view, with a spokesperson for the charity saying, "Much more research is needed before we recommend people engage with commercial companies who are banking stem cells."

Lack of evidence and independent information

The interest in tooth stem cell banking as a commercial proposition is particularly strong in the US, where dentists offer to collect extracted teeth and preserve the dental pulp stem cells. A review of this practice published in 2020 noted that information online was dominated by the companies offering the service.[3]

The websites of the companies and dental offices referred to in the review suggest possible future application for "pathologies as sweeping as diabetes, heart attack, cancer, autism, drug addictions, and aging." Yet the research quoted cites either clinical trials for non-dental mesenchymal stem cells or pre-clinical studies for dental derived stem cells.

"It is unclear whether this important difference is plain to even informed—but non-specialist—members of the public," the review says.

In the UK, while the laboratories extracting and storing the stem cells (see box 2) are regulated and inspected, Shepherd believes that more scrutiny of the information being used to promote the practice is needed. That is part of the ASA remit, but managing

health information can be difficult when it can easily be changed or added to a website and then taken down quickly, she adds.

"There isn't much information on tooth stem cell banking out there for consumers, and what is out there mostly comes from the companies who have an interest in selling their product. The Human Tissue Authority (HTA) has guidance for parents looking to bank cord blood[4]; it would be helpful to have guidance for dental pulp stem cell banking as well."

Shepherd also points out that the phrase "stem cell" is being used as a catch-all. Websites list many pages of research, but these are unlikely to be from dental derived stem cells. "It can be misleading. They use 'stem cell' as a term to get people to part with their money.

"Such decisions can be emotive for parents. But there isn't the information out there to inform them, and the regulators should take an active role."

A HTA spokesperson said, "The information on each party's website should be clear, accurate, and, where appropriate, evidence based, in line with UK advertising standards."

"Outrageous" autism claims

For some, the inclusion of autism in the list of conditions with potential for stem cell treatment is a red flag.

Tim Nicholls, assistant director of policy, research, and strategy at the National Autistic Society in the UK, said, "It's outrageous that tooth stem cell procedures are being advertised to parents with the false claim of 'treating' autism.

"Autism is not a disease or illness, it cannot be treated, and there is no cure. It is dangerous and morally bankrupt to target potentially vulnerable people with expensive procedures that could, in fact, cause harm."

He added, "There is no good evidence about stem cells and autism. There are also concerns about the regulation of stem cell procedures, which could be painful or even dangerous, depending on how they are administered."[5]

Shepherd also believes parents should be given more information on what type of tests are done to validate that stem cells are present in the stored samples, that the samples have been collected properly, and on how long such samples can be viably stored.

In a statement, Future Health Biobank says it has a "robust ongoing storage stability validation programme" with quality control testing "to ensure that there is no deterioration in the integrity, viability, or future potential of biological samples."

Three companies, many claims, one laboratory

The three companies offering the service in the UK operate through one laboratory, the BMJ investigation found.

Future Health Biobank purchased BioEden Group in 2019. Both have presence in countries around the world including the US and Switzerland and have "stored samples from thousands of UK and international families."

Stem Protect has little detail on its website about its ownership. A spokesperson tells *The BMJ* it is an independent company "partnered with Future Health Biobank, who handle all the logistics and banking of sample cells."

There is no listing on Companies House for Stem Protect but the spokesperson says the company is owned by Mark Hall. The responses came from Business Waste, a commercial waste management company that also lists Mark Hall as a director.

The HTA tells *The BMJ* that the laboratory run by Future Health Technologies was last inspected in November 2023. A spokesperson says, "Companies may operate multiple brands for commercial reasons while using a single licensed facility."

The BMJ has raised concerns about how the service is promoted on all three company websites with the ASA, including the details of samples being used in treatments and claims of how far advanced the research is in diabetes and autism. We also flagged that much of the research cited has not been done with stem cells from teeth. ASA says it will review our complaint and that in the meantime "the advertiser has been provided with details about the complaint and has been advised to amend their advertising and an objective claims that they do not hold adequate substantiation for."

An ASA spokesperson says it has previously ruled on claims related to stem cell banking but there have been no formal rulings on dental pulp stem cell banking adverts.

"We don't have specific guidance for businesses advertising tooth stem cell banking. But our general advertising rules, and our rules on medicines, medical devices, and health related products, would apply to advertisers in this sector.[6]

"This includes rules that advertisers must have evidence to back up any health claims made in their ad, and that medical claims can only be made for licensed products. Ads should be socially responsible and shouldn't discourage essential treatments for conditions for which medical supervision should be sought.

"And they also shouldn't mislead people by omitting key information or presenting information in an unclear way."

Future Health Biobank says that the examples given of use of stored samples were "customer testimonials relating to private applications of dental stem cells. These cases were not part of regulated UK clinical trials and we do not present them as such. A number of samples historically released by BioEden were processed for families based in Latin America, where a substantial part of the BioEden operation was located before it was acquired by FHBB."

The statement continues: "Releases may be used for various reasons, including within clinical trials abroad or as part of privately arranged treatments, depending on the jurisdiction and the medical providers involved. As such, outcomes may vary significantly, and we advise that such testimonials be viewed in this context.

"We are currently reviewing how historical information is presented online to ensure it reflects the correct geographic and regulatory context and that readers can clearly distinguish between client experiences and formally published clinical outcomes."

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I have read and understood BMJ policy on declaration of interests and have no relevant interests to declare.

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