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Collection of extracted human teeth in decline - Working knowledge and understanding of the Human Tissue Act by UK registered dentists.

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Running Title: Understanding and application of the HTA by UK dentists in collecting extracted teeth.

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SUMMARY

Introduction: For many years the dental profession has collected extracted human teeth for use in education and research. Since the enactment of the Human Tissue Act (HTA) in 2006 we have observed a fall in research outputs from the United Kingdom utilising extracted teeth for research.

Aims: To determine the working knowledge and understanding of the HTA of UK dentists who potentially could collect extracted teeth for use in teaching and research.

Design: A postal/online questionnaire.

Materials and Methods: A printed questionnaire and pre-paid return envelope, that sought to assess both the knowledge and understanding of the participants concerning the HTA as it applied to the collection of extracted teeth, was mailed out to 500 UK registered dentists. The potential participants were selected at random from the General Dental Council online registers.

Results: A total of 254 completed questionnaires were received (response rate = 50.8 %). Prior to September 2006 65.6 % of respondents had collected teeth. After this only 37.8 % did so. This was statistically significant ($P < 0.001$).

Conclusions: Confusion surrounded the collection and use of extracted teeth. This hampered dental education and research. To address this there is a need for clarity on the legal issues.

Introduction

For many years laboratory dental research has used extracted human teeth to test the performance of a diverse range of dental products and their application. A recent search of the published literature (Scopus Search Strategy [“in vitro” human teeth *; For 2000-2018; Limited to UK; Limited to Dentistry]), undertaken to support this work confined to papers published by UK based workers using such a model, suggests a decline in output (Figure 1). This could be for a variety of reasons for it is known that the number of dental extractions in the developed countries has fallen (1) thus depleting the number of teeth available for research. In addition, to avoid confounding factors tooth selection criteria generally look for similar fluoride exposure, age of tooth and storage medium as well as minimal damage during the extraction procedure (1). Another possible reason is the past Research Assessment Exercise and its succeeding Research Excellence Framework (REF), that seeks to assess research quality, and has been reported to both impact upon creativity and change the focus of research to accommodate a good institutional return (2). Perhaps also the enactment of the Human Tissue Act (HTA) (3) in 2006 has had unintended impact for this places upon researchers’ statutory responsibilities for the collection and use of extracted teeth in research. It is notable, as illustrated in in Figure 1, that post 2006 there has been a decline in outputs using extracted teeth. Forsyth and Woof (4) raised concerns at the time of enactment concerning the feasibility of collecting teeth for research in light of the HTA. It should be borne in mind that this act relates activities relating to the removal, storage, use and disposal of human tissues (defined as consisting of/or containing cells) and came into being as a result of public enquiries into post-mortem organ retention scandals at UK hospitals (Bristol Royal Hospital and Royal Liverpool Children’s Hospital). The Act however, does not apply to the collection of teeth for education (e.g. Teeth for Phantom Head practice), training or clinical audit providing that the teeth collected for such purposes are not to be used for research. As a consequence, many dental schools/universities have applied for and received a license for tissue storage and have also established protocols for the consent, collection

and issue of teeth for research. The impact of the strict regulatory nature of such protocols upon those involved is unknown but may be another factor in the decline of the output observed.

As the collection of teeth is pivotal to the needs of dental schools, to support research and teaching, this work sought to determine the knowledge and understanding of these regulations by those who may potentially collect teeth for such purposes. A low level of supply of appropriately collected teeth would frustrate these activities.

Materials and Methods

A questionnaire was designed according the principles of Dillman (5) and Lumsden (6) that sought to assess both the knowledge and understanding of the participants concerning the HTA as it applied to the collection of extracted teeth. This was piloted upon a convenience sample of potential future participants to ensure clarity of the final version. Following feedback and adjustment this together with the invitation letter was sent for an ethical opinion to the East of Scotland Research Ethics Service and also to the Research and Development (R & D) manager of the Tayside Medical Science Centre (TASC). The responses received indicated that under the terms of the Governance arrangements for Research Ethics Committee (GAFREC) in the UK ethical approval was not required nor NHS R & D approval. The invitation letter gave options for returning the completed questionnaire by either post (in a pre-paid envelope) or online using an online survey service tool (Bristol Online Surveys) with tracking disabled. It was mailed out to 500 UK registered dentists with a printed questionnaire and pre-paid addressed return envelope. Potential participants were selected at random from the General Dental Council online registers. No tracking of none responders or participants was possible and therefore responses were anonymous and no follow up was possible. The questionnaire sought information on

- Time since qualification as a dentist

- Country of primary dental qualification and if out with the UK date of first registration with the General Dental Council
- Whether/not they collected extracted teeth in their practice
- If extracted teeth were collected the reasons for doing so
- Estimated frequency of collecting extracted teeth pre and post 2006
- At the time of completion of the questionnaire estimated number of extracted teeth stored in the practice and the type of storage medium used
- If approached for what purpose (teaching/research) would the participant agree to collect teeth
- What consent was thought to be required for collecting teeth for education and research purposes
- In the past when the participant was developing their clinical skills how helpful was practising upon them. In addition, this part of the questionnaire looked at
 - Their experiences when seeking to collect such teeth from dentists
 - Knowledge of the current consent and legalities of collecting teeth for the purposes of dental research and dental undergraduate education.

All completed questionnaire responses were entered into a customised relational database (Paradox, Version 3.5, Borland International, USA) for subsequent interrogation of responses. Subsequent statistical analysis of the responses was undertaken using a proprietary statistical package (GraphPad Prism 6, GraphPad Software Inc., San Diego, USA) and Excel (Microsoft Excel, 2010, Microsoft Ltd., Reading, UK).

Results

In response to the invitation to participate a total of 254 completed questionnaires were received. This represents a response rate of 50.8 %. Mail was the preferred method of response (88.5 %, n =

225). The mean number of years since qualification was 21.2 (S.D. = 12.2) (< 10 years = 24.7 %, 10-20 years = 24.3 %, 20 – 30 years = 25.9 %, > 30 years = 25.1 %) and 84.6 % of respondents had qualified in the UK.

Prior to September 2006 65.6 % (n = 128) of respondents had collected teeth but after this date 37.8 % did so. This decline was statistically significant as demonstrated by both a chi-square and Fishers Exact test ($P < 0.001$). Reasons for collecting teeth put dental extractions foremost (46.3 %) followed by self-training/dental courses (27.3 %). Collecting for dental research on behalf of institutions was only carried out by 6 %. There were no statistically significant differences ($P > 0.05$) however in this practice between those who qualified in the UK and elsewhere. Other reasons stated for collecting were own collection e.g. Difficult extractions, rare cases, anomalies (16.4 %) and for clinical waste (6.0 %).

Sodium Hypochlorite was the most popular storage medium with dry storage next. Table 1 summarises the full range of storage media cited by the participants.

The majority of respondents would agree if approached to collect teeth for dental education (87.9 %) and research (86.6 %) but those stating they would refuse to do so were confined to those who had qualified prior to 2006 (12.1 % for dental education and 13.4 % for research).

The majority of respondents (79.1 %) had found during their undergraduate training practising upon extracted teeth very helpful and of these 59.6% found the people they approached to collect them on their behalf helpful.

Although acknowledged as required by the vast majority the level of consent required for tooth collection for teaching and research displayed much variation as is illustrated graphically in Figure 2.

Discussion

Before commenting upon the findings of the questionnaire a discussion of the return rate is warranted. The respondents were given the option to return the questionnaire either by post or

electronically. It was noted that on-line responses accounted for only 21.9 % of the total responses received. In an age where technology has replaced traditional forms of communication this was surprising but in accord with a study that sought the response preferences of healthcare professionals where 9.3 % were found to prefer on-line returns (7). Notwithstanding this a satisfactory overall return rate (50.8 %) was obtained that was in agreement with a meta-analysis of 45 published studies that had explicitly examined response the response rates of mail surveys (8). This was pleasing to see for it has been observed by others that geographically wide and random samples, as in the present study, result in lower return rates (8) and there is also said to be a downward trend in returning questionnaires (9). Although follow up letters are said to enhance response rates (10, 11) this was not practicable here for the respondents were anonymous. This was a policy adopted by the researchers from the outset of the study as it was desired to obtain as accurate a picture as possible of practice and knowledge of the HTA. The authors were of the view that making respondents identifiable would have hampered true disclosure. Perhaps the success or otherwise of this may be judged by the disclosure of storage media of extracted teeth in certain incompatible chemicals, with contemporary health and safety policies, being used such as formaldehyde and thymol. Although sodium hypochlorite was the most popular storage medium it should be borne in mind that its use could jeopardise the suitability of such teeth to undergo meaningful *in vitro* experiments, such as bond strength determination for such storage may reduce the composite to dentine bond strength (12). Some have advocated for such purposes 0.5% aqueous Chloramine T as a safe alternative to obviate such difficulty (13).

Although the majority of respondents would agree to collect teeth if approached by an institution it is interesting to note that those who would refuse all qualified before 2006. A possible explanation in that such dentists would have read the publicity that heralded the introduction of the HTA in the dental press and were both confused and more aware of its contents and ramifications than those who qualified after. Irrespective of the year of qualification however there was general confusion about what was required under the act. 90% of respondents made no distinction between research

and teaching teeth erring on the side of highest level of consent for both situations. Other cited misconceptions, placing upon the dentist additional unnecessary administrative burdens were the perceived needs for

- A HTA license to collect teeth for research (28.3 %)
- Traceability of collected teeth to donor (21.7 %).

Others (14), writing from an Australian legal perspective, have commented that dentists feel uneasy regarding the legal issues surrounding the retention of human teeth to use in dental education so this appears not to be just a UK issue.

The majority of respondents had found practising upon extracted teeth human teeth helpful in their undergraduate training and said they would be willing to collect teeth more readily if they understood the HTA better. Appropriate consent must be obtained for ownership of an extracted tooth rests with the patient unless consent is given for its retention irrespective of the purpose of use (15). If the dentist is to use extracted teeth for training, education or clinical audit storing teeth on the premises is permissible but if the teeth are to be used for ethically approved research purposes they must ultimately be stored on Human Tissue Act licensed premises with documented consent. It is therefore permissible for a dentist to collect for an institution to contribute to their licensed collection as the collected teeth will ultimately be sent to that institution.

In summary this work has identified confusion surrounding the collection and use of extracted teeth that appears to hamper both dental education and research. There is thus a need for better education which hopefully will increase the number of dentists collecting teeth. It is hoped that this paper brings clarity to the situation to facilitate this.

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Figure Legends

Figure 1 -A graph of the number of papers, involving UK institutions, that have utilised human extracted teeth in *in vitro* research from 2000-2018.

Figure 2 – Type of consent required for tooth collection for the purposes of dental education and research according to the respondents.

Figure 1 -A graph of the number of papers, involving UK institutions, that have utilised human extracted teeth in *in vitro* research from 2000-2018.

Figure 2 – Type of consent required for tooth collection for the purposes of dental education and research according to the respondents.

Table 1 – The storage media of extracted teeth cited by the questionnaire respondents who responded to this part of the questionnaire.

Storage Medium	n	% of Respondents using
Sodium Hypochlorite	35	44.3
Dry	25	31.7
Saline	5	6.3
Alcohol based solvent	4	5.1
Formaldehyde	3	3.8
Chlorhexidine	2	2.5
Other includes;	5	6.3
Hydrogen peroxide		
Thymol		
Ozonated tap water		
Sulphur granules		
Mercury suppressant fluid		

Footnote – not all responded to this part of the questionnaire.