



Report of Look-back Review into Orthodontic Services

Dublin Mid-Leinster, 1999-2002

Commissioner:
HSE National Director,
Community Operations

Date: April 2022

Reference Number: IIMS 50971

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Foreword

In 2019, the National Director, Community Operations commissioned the establishment of this Serious Incident Management Team to ensure that the full robustness of the HSE's Incident Management Policies and Look back Review Framework were applied to a historic incident. The incident was a Statement of Concern raised in 2012 relating to the Dublin Mid-Leinster Orthodontic Services more than a decade previously.

An investigation of the concern was undertaken in 2014-2015 by two UK based experts who concluded that patients were potentially harmed from care they received or did not receive in the service.

In response, a National Primary Care Incident Oversight Team was established in October 2015. It commenced the management of the incident in accordance with the HSE Safety Incident Management Policy (2014) and HSE Look-Back Review Process (2015). However, undertaking the full "look-back" required proved complex and despite much effort, planning and resources, the Primary Care Incident Oversight Team was unable to complete the full record retrieval and audit phase of the Look-back process.

This Serious Incident Management Team (SIMT) was commissioned by the National Director of Community Operations in 2019 to ensure that the incident management process that commenced in 2015 was completed and concluded through to patient recall stage if it was the case that any orthodontic patient was considered to have been potentially harmed.

This Report sets out in detail the background, methodology, and findings from the Look-back review under the governance of this Serious Incident Management Team.

The Look-back Review is described in three phases: Audit, Clinical Review and Recall/Open Disclosure. The purpose of the audit and clinical review stages was to identify those patients that had interrupted care, and to establish if there had been follow up treatment provided, particularly if problems had emerged during the interruption in treatment.

While the results presented from the Clinical Review report only on clinical issues and outcomes, it is clear that many young patients and their parents had poor experiences with the orthodontic service. In many instances, treatment was prolonged for a number of years beyond the original timeframe.

In the course of the Open Disclosure process, it was clear that the frustration, disappointment and dissatisfaction with the service recorded in the orthodontic records over 20 years ago continue to resonate with the patients and their families today.

The Chair and members of the Serious Incident Management Team would like to offer their sincere thanks to all patients and their families that met with the HSE during the Open Disclosure process.

On behalf of the HSE, we apologise to patients and families who were let down by our Orthodontic Services and experienced interruption in their care. While those events cannot be reversed, the HSE is fully committed to providing an honest record of what happened and in doing so it can avoid a recurrence of similar events in the future.



JP Nolan

*Chairperson, Safety Incident Management Team – Look back Review
Head of Quality & Patient Safety, HSE, National Community Operations*

2. Executive Summary

2.1 Introduction & Background

This report relates to the management of patients availing of, and requiring Orthodontic services in Dublin Mid-Leinster in the late 1990s and early 2000s.

In 2012, a formal concern was raised with the HSE that patients had their orthodontic treatment interrupted as a result of service provision issues there historically. This ‘Statement of Concern’ said that ‘children had been damaged by the HSE Orthodontic Services in Dublin Mid-Leinster more than a decade previously (circa mid-1999 to mid-2000)’.

The period under investigation in this report (1999-2002) was characterised by prolonged periods of service disruption, the loss of critical clinical capacity, and protracted difficulties between the clinical leadership of the service and Health Board management.

However, it is important to note that the reasons for the delays and interruptions were not part of the Terms of Reference of the Lookback Review process, and therefore not investigated by this Serious Incident Management Team. Those matters were examined in detail in the preparation of Oireachtas Reports on Orthodontics in 2002 and 2005.

In 2014, two UK experts were commissioned by the HSE to investigate the concern and advise accordingly. The specific intent of the commission was:

“The intention of this exercise is for the external reviewers to make a recommendation to the HSE in the context of patient safety and if further action would be warranted. The scope of this review is centred on patient safety.”

The UK experts submitted their report in 2015 and recommended that:

“To ensure accuracy, equity and transparency (in terms of who were offered or refused additional dental care), we would recommend that an investigation should be undertaken to look at the clinical records for those patients who were not seen for more than one year to document and categorise the oral health/orthodontic status, adverse effects and subsequent clinical management. It may be necessary to contact the patients to document their experience of overall care provided”.

The issue was regarded by the HSE as an ‘incident’ and a National Primary Care Incident Oversight Team was established in October 2015. This Oversight team commenced the management of the incident in accordance with the HSE Safety Incident Management Policy (2014) and HSE Look-Back Review Process (2015). However, undertaking the full “look-back” required proved complex and despite much effort, planning and resources, the Primary Care Oversight Team was unable to complete the full record retrieval and audit phase of the required Look-back process.

This Serious Incident Management Team (SIMT) was commissioned by the National Director of Community Operations in 2019 to ensure that the incident management process that commenced in 2015 was completed and concluded through to patient recall stage if it was the case that any orthodontic patient was considered to have been potentially harmed.

2.2 Methodology

This Look-back Review was carried out following the recommendation of the independent reviewers as stated at 2.1.

It should be noted however, that in the interests of patient safety, the parameters of the HSE's Look-back Review were more wide ranging than the recommendation in two respects:

- a. The period of investigation was extended to cover the period 1999 to 2002; the Statement of Concern related to the period "*circa mid-1999 to mid-2000*"
- b. The parameter for inclusion in the Look-back Review was an interruption in treatment of six months or more; the recommendation from the external experts had a threshold of an interruption of more than one year.

The Look-back Review is described in three phases: Audit, Clinical Review and Recall/Open Disclosure. The purpose of the audit and clinical review stages was to identify those patients that had interrupted care, and to establish if there had been follow up treatment provided, particularly if problems had emerged during the interruption in treatment. This would inform the decision of the SIMT in relation to patient recall and open disclosure.

Stages of the Look-Back Process

- A. **Audit:** to establish the full patient cohort for audit, and identify charts with details of treatment that was interrupted for six months or more.
- B. **Clinical Review:** to assess the impact for patients of interruptions of six months or more in their treatment. The threshold for recall was approved by the SIMT as:

"The patient was left with a permanent adverse effect that was not followed up or there is major clinical concern which warrants a recall."

In determining if a case met the threshold for recall, the Clinical Review Team applied four tests/key questions:

1. Was there an interruption in care of six months or longer?
2. Was there a permanent adverse effect relating to the interruption noted?
3. If there was an adverse effect, was it followed up?
4. Is there an outstanding clinical concern?

C. Recall and invitation to Open Disclosure

Under the continued governance of the SIMT, the purpose of Recall/Open Disclosure phase was to:

- A. Locate the patients identified for recall and ensure all reasonable steps were taken to locate them, in light of the passage of time and in compliance with data protection regulations.
- B. Conduct Open Disclosure in order to inform patients of their inclusion in the audit and the findings in relation to their care.
- C. Offer a dental assessment to patients in line with the Look-back Assessment Action/Work Plan and the requirements of the HSE Look-back Assessment Process Guideline.

- D. Identify actions to be taken as a result of the findings of the Recall stage of the Look-back Assessment Process.
- E. Implement remedial actions as appropriate, including individual treatment plans, and communicate any additional actions to be taken by the Commissioner of the Report and to communicate progress and outcomes to the Commissioner.

2.3 Outcome of the Look-Back Process

2.3.1 Outcome of the Audit of Charts from the period of interest

The audit commenced in 2015 subsequently restarted in October 2018 with the same methodology used throughout the process (see Appendix 4). 7,634 charts were audited to establish if they were within the scope of the Look-back review. Of the 7,634 charts, 492 were initially found to be within the timeframe and had evidence of interruption of care of six months or more. However, four charts were subsequently excluded as the period of interruption was outside of the period of interest in this review. Two charts were found to relate to the same person.

Therefore this report will detail the outcome of the clinical review of the records of 487 patients identified with an interruption in treatment of six months.

2.3.2 Outcome of Clinical Review of 487 records identified through Audit

Of the 487 cases considered by the Clinical Review team, 471 are considered to require no further investigation.

Sixteen cases were identified by the Clinical Review team as concerning and were presented to the Serious Incident Management Team for consideration of recall.

2.3.3 Decision of Serious Incident Management Team of 16 cases considered for Recall

In October 2019, the Clinical Review team presented the findings of their review including a detailed case report on each of the sixteen cases considered to be of concern. A decision was then made by the full SIMT about the need for recall in each case. The decisions of the SIMT were unequivocal. Each of the sixteen cases warranted recall and follow up.

The SIMT concluded that:

“Every reasonable effort should be made to contact these patients and undertake full Open Disclosure with each individual. Following disclosure each patient will be offered a clinical assessment and implementation of any appropriate treatment plan required.”

The SIMT anticipated challenges in making contact with the patients given the extended passage of time.

2.3.4 Outcome of Recall/Invitation to Open Disclosure

On completion of the Audit and Clinical Review Stage of the Look Back Review, sixteen patients were found to have met the threshold for recall. The task of locating the patients involved undertaking searches of databases held by the HSE (Primary Care Eligibility & Reimbursement Service (PCERS) and the Civil Registration Service (CRS)), and those held by the Department of

Employment Affairs and Social Protection (DEASP). It also involved making contact with Hospitals and General Practitioners (GPs), as recorded on individual patient files. The process of locating the sixteen recall patients took place between January 2020 and August 2021. All stages of the Recall/Open Disclosure phase were carried out in accordance with data protection regulations, cognisant of the rights of individuals to dignity, respect and confidentiality. The onset of the COVID 19 pandemic during the recall phase led to delays in completing the task of locating patients.

Summary of Open Disclosure & Concluding Patient Status

The process of locating the addresses for the sixteen patients identified for Recall involved three phases over a period from January 2020 – August 2021. None of the searches undertaken indicated that any of the sixteen patients were since deceased.

Of the Sixteen Patients identified, ten engaged with the Recall Team for Open Disclosure. In this group of patients a range of clinical outcomes emerged during the open disclosure meetings. The clinical outcomes ranged from treatment not commenced, treatment not completed, to treatment completed within the service or completed privately.

Each of the ten patients was offered a dental assessment in line with the terms of reference. As appropriate, treatment plans were initiated in accordance with clinical need and the informed wishes of the patient.

All of the patients that engaged in the Open Disclosure process received an apology on behalf of the HSE.

2.4 Patient experience

Impact of delays and interruption of treatment

The HSE would like to highlight the inconvenience, worry, anxiety and difficulties that patients and their families experienced in this service during the period under review due to delays and interruption in their care. This was clearly evidenced in the records reviewed, whereby patients or their guardians voiced dissatisfaction and frustration with little response from the service.

Many families opted out of the system and sought treatment elsewhere. The review team acknowledge that many others could not or did not know how to access alternative care. It was evident from some charts that the request by patients to have their appliances removed was due to frustration in the length of time the treatment was taking.

In the majority of cases where treatment was interrupted, satisfactory outcomes were achieved when treatment was recommenced and completed.

While the results presented from the Clinical Review report only on clinical issues and outcomes, it is clear that many young patients and their parents had poor experiences with the orthodontic service. In many instances, treatment was prolonged for a number of years beyond the original timeframe.

In the course of the Open Disclosure process, it was clear that the frustration, disappointment and dissatisfaction with the service recorded in the orthodontic records over 20 years ago continue to resonate with the patients and their families today.

The impacts of delays and interruptions to treatment on this group of patients and their families were negative and serious. Many of the patients experienced delays and prolonged interruptions in treatment for complex malocclusions that affected their appearance. In a number of instances, patients and their families didn't know if treatment would continue, and assumed that they had aged out of the system.

Some described the personal impact of being left untreated after several years attending the service, while others spoke of the prolonged negative effects of not starting treatment on their sense of wellbeing during their teenage years. In the course of some open disclosure engagements a number of patients spoke of the adverse impact on their lives of delays and interruptions in their care. Some recounted their experience of being bullied, having low self-esteem and a lack of confidence in their appearance.

Facial characteristics and appearance are significant influences on self-perception and self-esteem for children and adolescents. Teasing or bullying of young people due to the appearance of their teeth has been frequently reported in clinical research (Seehra et al, (2011)¹, Scheffel et al, (2014)², Smyth, PhD Thesis (2021)³); those affected have legitimate expectations that successful orthodontic treatment could have a positive impact on their self-perception and self-esteem.

From the Open Disclosure process, it is evident that these expectations were not met for some patients whose treatment did not commence. For others whose care was interrupted, the prolonged and unacceptable timeframe of their treatment delayed the anticipated benefits.

The members of the Serious Incident Management Team would like to offer its sincere thanks to all patients and their families that met with the HSE during the Open Disclosure process.

2.5 Apology

On behalf of the HSE, we wish to express our deep regret and sincerely apologise to all of those who were let down by our Orthodontic Services and experienced delays and interruption in their care.

2.6 Conclusions

The priority of this look back review was patient safety. The review was undertaken to identify those patients who had an interruption to their orthodontic treatment between the years 1999-2002 and to initiate a recall/open disclosure process for patients that met the clinical threshold for recall. The recall/open disclosure phase included offering a clinical assessment and implementation of treatment plans as required.

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- 1 Bullying in orthodontic patients and its relationship to malocclusion, self-esteem and oral health-related quality of life; (2011) Seehra, J., Fleming, P.S, Newton, T., DiBiase, A.T. *Journal of Orthodontics*, Vol. 38, 2011, 247–256.
 - 2 Esthetic dental anomalies as motive for bullying in schoolchildren; Scheffel, D.L.S.; Jeremias, F.; Fragelli, C.M.B.; Martins dos Santos-Pinto, L.A.; Hebling, J.; de Oliveira Jr, O.B *Eur J Dent.* 2014 Jan-Mar; 8(1): 124–128.
 - 3 Smyth, J. P. R. (2021). Adolescent and parent perceptions of expected benefits of orthodontic treatment: a mixed-methods study. PhD Thesis, University College Cork.

As documented, the lookback review took several years to complete due to the complexity of the issue, changes in HSE management structures and a protracted and detailed process of Audit and Clinical Review. This look back review process has revealed that 487 patients had delays or interruptions in their treatment of six months or more, with sixteen of those patients identified for recall.

The process of locating the addresses for the sixteen patients identified for Recall involved three phases over a period from January 2020 – August 2021. Of the Sixteen Patients identified, ten engaged with the Recall Team for Open Disclosure. The Recall Team were unable to locate and engage with six of the patients, despite undertaking extensive searches.

Section 7.1 outlines the impact of delays and interruptions in orthodontic treatment on patients and their families; the conclusions of the SIMT strongly reflect the patient experience as recorded in the records reviewed by the Clinical Review Team and subsequently confirmed by the patients that engaged in the open disclosure process.

In reaching these conclusions, the SIMT has taken account of the examination of the records, its documentation and categorisation of the oral health/orthodontic status, adverse effects and subsequent clinical management of the patients whose care was delayed and interrupted, and the reported experiences of the patients that engaged in open disclosure.

The combination of the review of the records by the Clinical Review Team and the accounts of personal experiences of the patients given to the Recall Team during open disclosure confirm that the period under investigation was characterised by unacceptable delays and interruption of treatment.

The process of reviewing clinical charts involved retrieval of archived records. Paper based records were in use during the period under investigation, which revealed that:

- i. During the review process there was limited evidence found of a systematic approach to archiving records. In some instances there appeared to be an ad hoc approach and records were sent for storage when the opportunity arose. From time to time chart filing space within the department was an issue and old, completed, dormant or discharged files would be sent to data storage facilities off site. Charts were randomly placed into storage boxes and sometimes mixed in with study model boxes. The ad hoc practice in the unit was that not all storage box numbers were entered on the patient records. Routine procedures when preparing clinical charts and records for offsite storage is that a catalogue is retained of all charts/records placed in the storage box which has a bar code. Thus a record is retained within the department to facilitate chart retrieval if necessary.
- ii. The review of the records revealed that charts/clinical records were not routinely signed by the treating clinician. Normal practice at the time was to sign or initial all entries.
- iii. There was no consistency of filing study models with the patient chart number. Study models were filed separately.

In the majority of cases where treatment was interrupted, satisfactory outcomes were achieved when treatment was recommenced and completed. Many of the patients that experienced adverse effects had these treated satisfactorily in the period following the interruption in their treatment.

However, the look back review of patient records identified a cohort of sixteen patients for recall and open disclosure.

The outcome of the Audit, Clinical Review and Recall/Open Disclosure phases of the look back review have left the SIMT with no doubts about the negative and serious impacts of the delays and interruptions in Orthodontic treatment on the young patients involved and their families. This group of patients and their parents were let down by the service. This was clearly evidenced in the records reviewed, whereby patients or their guardians voiced dissatisfactions and frustrations with little response.

Recommendations arising from the conclusions of the SIMT including the mitigation of risk of harm and/or poor patient experiences and the management of clinical records are presented below.

2.7 Recommendations

In the context of the report's finding and conclusions, the SIMT make the following recommendations to address identified risks and to progress effective care and patient safety within the Orthodontic Service:

2.7.1 Patient Experience

As evidenced in the records reviewed, patients and their guardians voiced dissatisfaction and frustration with the service. Patients and their advocates must have a meaningful voice in relation to planning and delivery of Orthodontic services.

It is recommended that feedback received from 'Your Service, Your Say' in relation to the Orthodontic Service including complaints is monitored as part of the Quality & Patient Safety governance arrangements and actions arising implemented.

2.7.2 Clinical Governance

The Lookback Review has revealed historical deficits in the clinical governance structures and process within the DML Orthodontic Service. While the analysis of these deficits was outside the scope of this look back review, the impact on effective patient care and safety must be noted as a risk to patient safety.

It is recommended that the HSE must strengthen Clinical Governance structure, processes and Clinical Leadership in its Orthodontic Services.

It is recommended that senior management and lead clinicians establish and fully participate in quality and patient safety governance structures, processes and training.

2.7.3 Audit

It is recommended that the Clinical Audit Programme for the Orthodontic Service be updated and strengthened to take account of the findings of this Look Back Review and include cyclical reporting of the outcome of treatment provided using the 'Peer Assessment Review' (PAR) system and other appropriate audit tools.

2.7.4 Training

- i. It is recommended that senior management implements appropriate training in quality patient safety procedures for all staff.
- ii. It is recommended that all staff involved in dealing with patients should have training and support in managing challenging situations, delays in treatment and complaints.
- iii. It is recommended that all staff should undergo necessary cyclical training in all relevant HSE policies and procedures including records management and retention and the use of email.

2.7.5 Record Management

In response to the findings of the look back review, the following recommendations are made:

- i. The HSE should ensure that the roll out of the electronic national clinical records system to all regional orthodontics services is completed as soon as possible. The Individual Health Identifier (IHI) number should be used on all records created for each patient.
- ii. Full digitalisation is required of all Orthodontic clinical records including clinic visits for assessment, diagnosis, treatment planning and clinical treatment, as well as radiographic images and study models.
- iii. Standardisation of record back-ups and archiving of records should be an integral part of the electronic clinical records management system.

In response to the finding of the impacts of delays and interruptions in treatment, the following recommendations are made:

2.7.6 Treatment interruption alert system

In order to minimise the possibility of undetected adverse effects during orthodontic treatment, an alert system of successive failed appointments should be established, as well as warnings of “in treatment, no appointment scheduled”, repeated cancellations, and an alert threshold of 4 months for those with appliances.

2.7.7 Management and the Clinical Leadership of HSE Orthodontic Services must be cognisant of the potential for adverse effects to arise for patients whose Orthodontic treatment is interrupted for a sustained period of time and take timely and appropriate decisions to mitigate these risks.

In line with the terms of reference of this SIMT, the report including its recommendations will be presented to the Commissioner of the look back review.

3. Introduction and Background

3.1 Chronology

In 2012, a formal concern was raised with the HSE that orthodontic patients in Dublin Mid-Leinster had treatments interrupted or neglected as a result of service provision issues there historically. This 'Statement of Concern' said that 'children had been damaged by the HSE Orthodontic Services in Dublin Mid-Leinster more than a decade previously'; (circa mid-1999 to mid-2000).

In 2014, the HSE commissioned two UK experts to review the Statement of Concern, explore the validity of the concern and advise accordingly. The UK experts submitted their report in 2015 and recommended that the HSE would investigate the clinical records from that period, and recall patients if that proved necessary.

The issue was regarded by the HSE as an 'incident' and a National Primary Care Incident Oversight Team was established in October 2015. This Oversight Team commenced the management of this incident in accordance with the HSE Safety Incident Management Policy (2014) and HSE Look-Back Review Process (2015). However, undertaking the full "look-back" required proved complex and despite much effort, planning and resources, the Primary Care Oversight Team were unable to complete the full record retrieval and Audit phase of the required Look back process.

This Serious Incident Management Team (SIMT) was commissioned by the National Director of Community Operations in 2019 to ensure that the incident management process that commenced in 2015 was completed and concluded through to patient recall stage if it is the case that any Orthodontic patient was considered to have been potentially harmed.

3.2 Scope of the Look-back Review

Scope of the Review – determined by the Terms of Reference (Appendix 1) which were based on the Recommendation of the External Reviewers:

"To ensure accuracy, equity and transparency (in terms of who were offered or refused additional dental care), we would recommend that an investigation should be undertaken to look at the clinical records for those patients who were not seen for more than one year to document and categorise the oral health/orthodontic status, adverse effects and subsequent clinical management. It may be necessary to contact the patients to document their experience of overall care provided".

1. The scope of the review of records was determined by the Terms of Reference and limited to the available clinical records.
2. The period of investigation was extended to cover the period 1999 to 2002; the Statement of Concern related to the period "circa mid-1999 to mid-2000".
3. The Terms of Reference for the review of records expanded the scope of the review by including clinical records of patients who were not seen for more than six months rather than one year.
4. The review sought to find the records of all patients within the defined time period that had experienced interruptions and delays in their treatment in excess of 6 months.
5. The review did not examine the reasons why delays and/or interruptions to treatment occurred.

6. The review was not an assessment of any individual's practice or professional competence.
7. The effect of hindsight bias and outcome bias is acknowledged by those conducting the review.
8. The clinical records may not have contained details of all phone calls or complaints about delays in services. In line with the Terms of Reference, the review deals only with the content of the records.

The period under investigation was characterised by prolonged periods of service disruption, the loss of critical clinical capacity, and protracted difficulties between the clinical leadership of the service and Health Board management.

However, it is important to note that the reasons for the delays and interruptions were not part of the Terms of Reference of the Look-back Review process, and therefore not investigated by this SIMT. Those matters were looked at in detail in the preparation of Oireachtas Reports on Orthodontics in 2002 and 2005.

3.3 Orthodontic Services in Dublin Mid-Leinster

Orthodontic Services in Dublin Mid Leinster during the period of investigation

The Regional Orthodontic Service for the Eastern Health Board opened in Autumn 1996.

Orthodontic treatment in the unit was restricted to cases with severe malocclusions necessitating complex treatment plans. All treatment cases involved assessment for eligibility, examination and treatment planning, provision of active treatment, followed by retention. A typical course of treatment was in excess of three years, with return visits on a 4-6 weeks basis during active treatment, and at a lower frequency during retention.

At the start of the period of investigation, service to patients was provided through a Consultant Orthodontist led model of care, including in service training of dentists to become specialists under the supervision of the Consultant Orthodontist. This meant that the Consultant Orthodontist supervised the work of the practitioners working in the Regional Orthodontic Unit. The clinicians were supported by a team of dental nurses and administrative staff.

3.4 Clinical Overview

In the course of orthodontic treatment, adverse effects can emerge. Some, but not all of these can relate to the treatment, for example a problem with an orthodontic appliance.

Orthodontic treatment carries risks and the possibility of unintended effects on the dentition. Such effects can include root resorption (shortening/loss of the root), pulpal (internal) changes, periodontal (gum and bone loss) disease, and temporomandibular dysfunction (joint pain). Generally, the consequences can increase with the duration of treatment and this is especially true for issues such as root resorption.

Others are coincidental in their timing, and may be the result of pathology that was developing prior to the orthodontic treatment, or are related to the oral health and hygiene of the patient during treatment. These include decalcification (white spots) which may proceed to dental caries with cavitation (tooth decay).

The Orthodontic Services in Dublin Mid-Leinster in 1999 to 2002 did detail the risks of undergoing Orthodontic Treatment to patients and their guardians in a consent form used before treatment was commenced (Appendix 3). It included references to the possibility of problems emerging during treatment, and emphasised the importance of optimal oral hygiene and minimal sugar intake by patients during their treatment. The form however, does not explain the risks consequent to delays in or interruptions to treatment.

3.5 Retrieval of patient records for review purposes

Prior to the commencement of the Audit, serious difficulties arose when efforts were made in late 2014 to identify the cohort of patients potentially affected by delays and interruptions in their treatment. The computer based systems could not identify specific records of patients who were under treatment during the period of interest, nor was there a systematic listing maintained of patients whose treatment was interrupted, or may have been interrupted. The cohort of patients involved could not be readily identified from the manual or computerised systems. Also, the records stored off site did not readily identify which charts and study models were stored in each box.

It is important to note the following in relation to the records reviewed in this Look-back review:

- In the period of interest from 1999-2002, records at the Regional Orthodontic Department were held in A4 card/paper format. Computer systems were in use for only part of this time, but clinical records were not logged on these systems.
- Therefore, a typical patient chart was a plastic A4 sized wallet which contained numerous A4 cards, loose-leaf continuation sheets detailing the records of each visit to the department over the period of treatment (likely to be over 20 visits) as well as photographs/slides, the original referral letter and other letters relating to the case. Radiographs for each patient were stored in paper envelopes within the plastic wallet. Patient records included an identifier relating to the origin of the referral on a county basis, i.e. Dublin, Kildare and Wicklow.
- It appears that in some cases photographs/slides and study models were stored separately to the main paper record, and in some instances a different record number was assigned to these items. Reconciling these records involved checking numerous index systems and books.
- Inactive records were put into off site data storage with private companies. This was done when storage space in the department was an issue and on an opportunistic basis as time allowed.
- An IT system was set up in the Regional Orthodontic Department in 2001. It was a basic filing system for charts and patient records. In July 2005 a new IT system was introduced and patient records were transferred to it from the older system. This new IT system retained the county identifier.

Consequently, the retrieval of records for this Look-back Review necessitated locating and lifting the lid on all 885 jumbo size boxes in storage in order to find the charts of patients within the scope of the review.

4. Planning and Methodology

4.1 Preliminary Risk Assessment to establish the need for Look-Back Review

Look-back reviews are carried out when a health service makes a decision based on a robust risk assessment process to review the care or treatment provided to a specific group of people using a service. This re-examination is usually done when it is considered that the results delivered by either a service or an individual may not have been up to the standard which would be expected when benchmarked against available international norms.

The HSE commissioned an external review of the Statement of Concern in 2014. The Terms of Reference for the External Review include, inter alia, the following:

“The intention of this exercise is for the external reviewers to make a recommendation to the HSE in the context of patient safety and if further action would be warranted. The scope of this review is centred on patient safety.”

The following recommendation was received by the HSE’s National Primary Care Division in February 2015 from the external review:

“To ensure accuracy, equity and transparency (in terms of who suffered damage and who were offered or refused additional dental care), we would recommend that an investigation should be undertaken to look at the clinical records for those patients who were not seen for more than one year to document and categorise the oral health/orthodontic status, adverse effects and subsequent clinical management. It may be necessary to contact the patients to document their experience of overall care provided.”

The Incident Management Oversight Team responded by taking a decision that the review should proceed to an audit of all patient records to establish those patients that were deemed to have potential adverse effects arising from interruption in treatment with the Orthodontic Services in Dublin Mid Leinster Region between 1999 and 2002. Therefore, the period of investigation to be undertaken was wider than the period referred to in the Statement of Concern.

It should be noted that the HSE Incident Management Oversight Team also broadened the parameters of the cases to be reviewed beyond that recommended by the external reviewers by including all cases where there had been an interruption in orthodontic treatment of six months or more.

4.2 Identifying the group of patient charts to be reviewed

There were considerable logistical requirements for the review of historical patient records as already detailed in this report.

The period in question was agreed as 1999-2002. The first objective was to identify patients seen and treated during this time. Records relating to this timeframe had been sent in boxes to an offsite data storage facility. There were 885 jumbo boxes in the offsite facility which could have contained records related to this time period. Therefore all boxes needed to be opened and checked to establish if they were relevant to this look-back review.

The entire patient chart identification and retrieval project was undertaken by a Senior Dental Nurse who led a team of clerical administrative staff and dental nurses with guidance and oversight from the National Oral Health Lead.

The audit that commenced in 2015 was subsequently restarted in October 2018 under the guidance of the National Oral Health Lead. The audit methodology is recorded and was the same throughout the process.

4.3 Establishment of the Serious Incident Management Team (SIMT) 2019

The SIMT was commissioned to progress the look back review and bring the process to a conclusion as per their Terms of Reference (Appendix 1).

The action of the SIMT was to establish a team of clinicians to undertake the clinical review phase of the look-back. To that end, the National Oral Health Lead formed a Clinical Review Team. This Clinical Review Team reviewed the clinical records of patients identified at the Audit Stage as having had an interruption in treatment of 6 months or longer.

4.4 Review Methodology

There were two stages in the process:

- a. The **audit stage** to identify cases where there had been an interruption in care in excess of six months.
- b. The **clinical review stage** where each chart was reviewed to determine if any adverse effects were noted in the chart, if these adverse effects were adequately followed up, or if there was an outstanding clinical concern.

4.5 Audit Stage

The Audit stage was undertaken in two tranches: February 2015 to June 2015 and October 2018 to February 2019, with the same methodology for identifying interruption of care (see Appendix 4). The numbers set out in this report represent the combined results of both tranches.

4.6 Audit Process

Charts were retrieved from an offsite storage facility. Each chart was then reviewed to see if the patient was treated in the time frame and/or if treatment was interrupted. All information captured from the charts was recorded contemporaneously in line with relevant data protection regulations.

4.7 Clinical Review Process

The clinical review of charts sought to determine if they contained details of “adverse effects” which may have been associated with the interruption of orthodontic treatment (see Appendix 5). Adverse effects were noted by the clinical reviewer if they had been observed after the interruption period, and could have been associated with the interruption of care. For example, dental caries (tooth decay) noted before the interruption in treatment or a number of years after resumption of service was not included. A quality assurance process was conducted during the review process to ensure reproducibility of recording of adverse effects.

All adverse effects noted by the clinical reviewer had been recorded in the patient charts by the treating clinician.

Prior to the review, a template was developed to record adverse effects. This contained a list of adverse effects that can be associated with orthodontic treatment such as root resorption, decalcification, tooth decay, periodontal disease and gingival conditions which may occur unmonitored if there was an interruption to service.

An additional category titled “Other” was included to capture any other adverse effect not listed in the template.

On completion of the clinical review it was decided to further sub-categorise the “Other” adverse effects as many of the charts that fell into this category contained similar issues.

These are set out in tables below.

Table 4.7.1

Categorisation of Adverse Effects
<ul style="list-style-type: none"> • TOOTH WEAR – Abnormal Wear or Loss of Tooth Substance – which can be associated with the appliance or to the interruption of orthodontic treatment
<ul style="list-style-type: none"> • TOOTH DECAY – Tooth Decay – note the extent
<ul style="list-style-type: none"> • DECALCIFICATION – Enamel Decalcification – note the extent
<ul style="list-style-type: none"> • PERIO-GINGIVA – Periodontal Disease and/or Gingival conditions – Periodontal disease resulting in pocketing/crestal bone loss and/or other gingival/mucosal conditions associated with poor oral hygiene
<ul style="list-style-type: none"> • RESORPTION – External Apical Root Resorption (ARR) – radiographic evidence of shortening of the root length
<ul style="list-style-type: none"> • TMD – Temporomandibular Joint Dysfunction (TMD) – persistent TMD
<ul style="list-style-type: none"> • ASPIRATION – Aspiration or Ingestion of Orthodontic Appliances
<ul style="list-style-type: none"> • INJURIES – Patient Injuries from Orthodontic Appliances – other permanent/significant intra or extra oral injury caused by the orthodontic appliance
<ul style="list-style-type: none"> • PAIN – Pain and Discomfort – where a significant issue was noted
<ul style="list-style-type: none"> • OTHER – Other Relevant Clinical Notes

Table 4.7.2

Sub-categorisation of “Other” Adverse Effects
• APPLIANCE – Issue with appliance
• INCOMPLETE TREATMENT PLAN – Incomplete treatment (further planned treatment or 2nd phase of treatment not carried out)
• UNFINISHED TREATMENT – Unfinished treatment (Patient under treatment, multiple missed appointments recorded as ‘DNAs’ or no further record of attendance)
• DEBOND – Request for debond by patient before treatment is completed
• TREATMENT NOT COMMENCED – Assessment completed but treatment not commenced
• ORTHO ISSUE – Orthodontic issues (e.g. Space loss, too much space created)
• MISCELLANEOUS – Miscellaneous

Threshold for recall

The threshold for recommendation for a patient to be considered for recall was determined by the SIMT as follows:

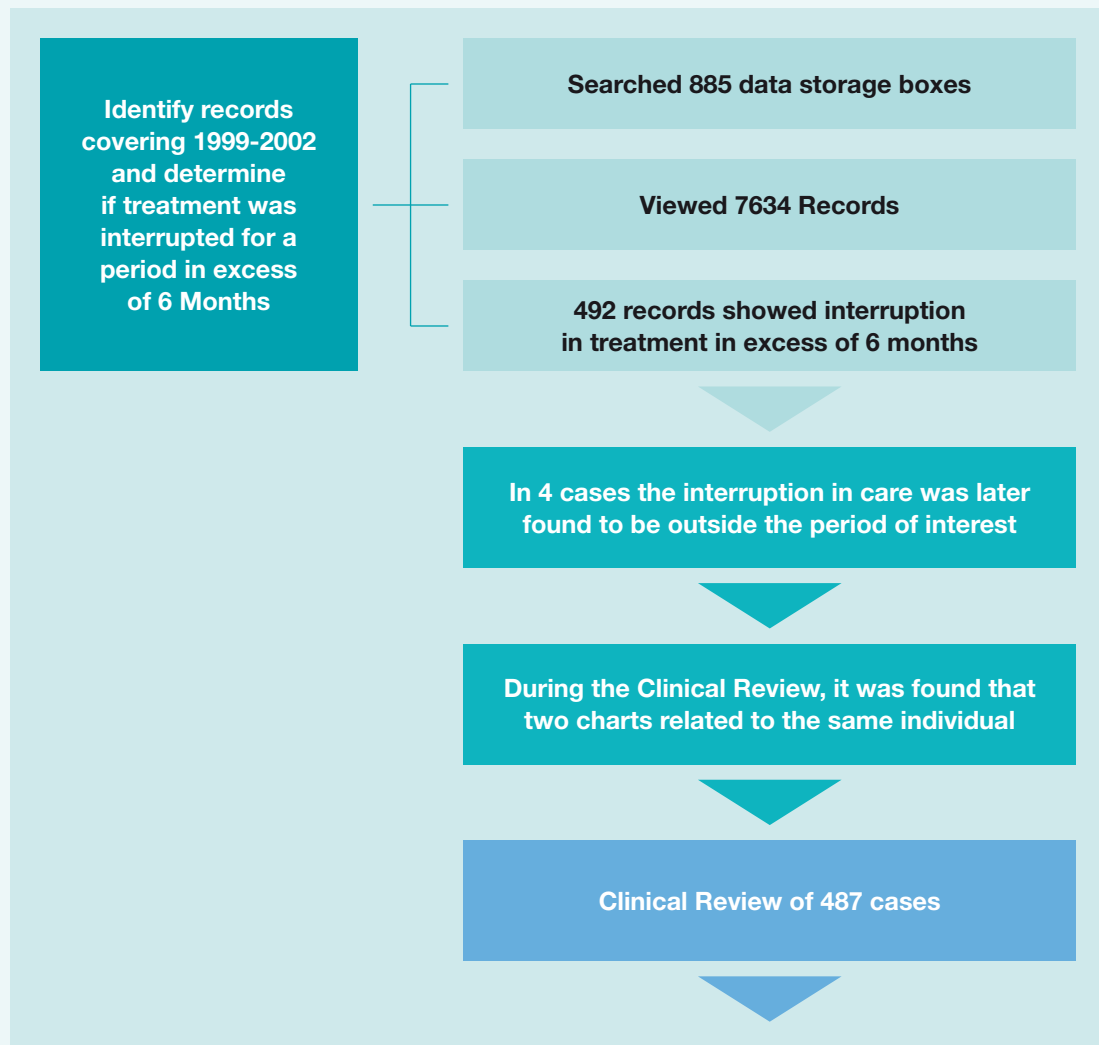
“Records indicate that the patient was left with a permanent adverse effect that was not followed up or there is major clinical concern which warrants a recall”

In determining if a case met the threshold for recall, the Clinical Review Team applied four tests/key questions:

1. Was there an interruption in care of 6 months or longer?
2. Was there a permanent adverse effect relating to the interruption noted?
3. If there was an adverse effect, was it followed up?
4. Is there an outstanding clinical concern?

5. Outcome of Audit and Clinical Review Processes

Chart 5.1 Outcome of Audit process



Clinical review phase

In determining if a case met the threshold for recall, the Clinical Review Team applied four tests/key questions:

1. Was there an interruption in care of 6 months or longer?
2. Was there a permanent adverse effect relating to the interruption noted?
3. If there was an adverse effect, was it followed up?
4. Is there an outstanding clinical concern?

Recording of adverse effects

The tables below set out the number of instances in which the clinical reviewers found adverse effects noted in the charts of the 487 cases reviewed. As outlined in **Section 4.7, Clinical Review Process**, a template was developed to record adverse effects. This contained a list of adverse effects that can be associated with orthodontic treatment, and which may occur unmonitored if there was an interruption to service. An additional category titled “Other” was included to capture the details of any other adverse effect not listed in the template.

On completion of the clinical review it was decided to further sub-categorise the “Other” adverse effects as many of the charts that fell into this category contained similar issues. This was necessary in order to accurately report on a number of cases.

Of the 193 charts with adverse effects noted, there was a single adverse effect in 153 cases, while 40 cases had two or more adverse effects noted.

Table 5.1 contains details of the number of instances of adverse effects found. However, it should be noted that the report on the “other” category is the number of cases, as this data was gathered prior to the sub-categorisation outlined above. The breakdown of instances of the “other” sub-categories is shown in Table 5.2.

Table 5.1

** Breakdown of instances of adverse effects by category	
Tooth wear	1
Tooth decay	24
Decalcification	20
Perio-Gingiva	22
Resorption	14
TMD	5
Aspiration	0
Injuries	0
Pain	11
* Other (no of cases)	146

* Reported as number of cases.

** It should be noted that some charts contained instances of several adverse effects; therefore arithmetical calculation of this data is not advised.

Table 5.2

** Breakdown of instances of “Other” adverse effects found in 146 cases by sub-category	
Issue with appliance	88
Incomplete Treatment Plan	14
Unfinished Treatment	8
Debond requested by patient	27
Orthodontic Treatment not commenced	14
Orthodontic issue	44
Miscellaneous	9

Summary of “Other” Adverse Effects

Of the 193 charts with adverse effects noted, 146 cases were found to have one or more adverse effects under the category designated as “Other”. The following is a summary of “Other” adverse effects in the 146 charts.

Issues with the appliance

The most common issue observed in the charts that had “Other” adverse effects was an issue with the appliance. Eighty eight of the charts showed that the patient presented as an emergency or at a scheduled appointment with an issue with his or her orthodontic appliance after the interruption period. Examples of issues reported include:

- Brackets off or not engaging the arch wire
- Arch wire out or loose
- Missing bands and modules
- Fractured removable appliance

The records show that the issues with appliances were dealt with on presentation or shortly afterwards.

Incomplete treatment plan

Fourteen charts showed that there was further planned treatment or second phase of treatment that was not carried out. Orthodontic issues were also noted in eleven of these charts and two of the patients requested an early debond before the treatment was complete. Six of the charts with further planned treatment or second phase of treatment not carried out contained another two recorded adverse effects under “Other” (e.g. issue with the appliance, orthodontic issue or early debond).

Unfinished treatment

Eight patient charts showed that the patient was under treatment but there was no record that the treatment was finished. These patients had typically failed to attend for their last appointment (DNA)

and were given follow up appointments but after multiple recorded DNA's there was no further record of attendance. Two of these eight charts also showed an issue with the appliance when patient presented after the interruption.

Request for debond by patient

Twenty seven patients had their appliances removed before treatment was completed at their own request and insistence. Many, (but not all) of these charts contained a signed declaration by the patient/parent confirming that they were requesting debond although the treatment was not finished.

It was evident in some charts that the request by patients to have their appliances removed was due to frustration in the length of time the treatment was taking.

Requests by patients to have an early debond were noted in some other charts but are not included here as the patients continued to wear their appliances and went on to have their treatment finished.

Additional orthodontic issues were noted in eleven of the twenty seven patients that requested and had their appliances removed early. Two of these patients also had further planned treatment or second phase of treatment that was not carried out. Fifteen of these charts also showed an issue with the appliance when the patient presented after the interruption.

Assessment completed but treatment not commenced

Fourteen charts showed that the patient had completed an orthodontic assessment but treatment was not commenced.

Orthodontic issues

Orthodontic issues were highlighted in forty four charts. In majority of these charts there was also an issue with the appliance noted after the interruption to service. Eleven of these charts were associated with having had "Incomplete Treatment" i.e. there was further planned treatment or second phase of treatment that was not carried out. Orthodontic issues were also noted by the reviewers in eleven patients that requested and had an early debond. Eight out of the forty four charts were recorded as showing a combination of three different "other" issues.

Miscellaneous

A range of "other" issues was recorded in nine patient charts. One of these charts was also recorded as having an issue with the appliance after interruption. The miscellaneous cases are summarised below:

- Two patients required root canal treatment on a tooth after a period of interruption. Both patients were referred for treatment and followed up until discharge.
- Persistent mobility was noted on an anterior tooth during the retention phase of treatment. Patient was due to be seen again but no other recorded attendance.
- Issues caused due to the interruption of service for two patients needing Orthognathic treatment.

- Some skeletal asymmetry was noted after nearly eight months of interruption but the patient requested debond as they were happy with the alignment of the teeth and did not want further appointments in the orthodontic unit; however records indicate that the patient continued treatment privately.
- Patient had debond before interruption and had retainers fitted but did not have any reviews due to the interruption to service. Patient was then sent three appointments two and half years later but did not attend.

Outcome of Clinical Review

Threshold for recall

The threshold for recommendation for a patient to be considered for recall was determined by the SIMT as follows:

“Records indicate that the patient was left with a permanent adverse effect that was not followed up or there is major clinical concern which warrants a recall”

In determining if a case met the threshold for recall, the Clinical Review Team applied four tests/key questions:

1. Was there an interruption in care of 6 months or longer?
2. Was there a permanent adverse effect relating to the interruption noted?
3. If there was an adverse effect, was it followed up?
4. Is there an outstanding clinical concern?

Of the 487 cases found to have an interruption in treatment of six months or longer that were considered by the Clinical Review Team, 294 had no adverse effects noted, and were eliminated from further enquiry.

With regard to the 193 cases found to have adverse effects noted, 177 are considered to require no further investigation.

Therefore, in summary, **471** of the **487** charts reviewed with interruptions in treatment of six months or more are considered to require no further investigation, as they did not meet the tests for recall i.e. that no adverse effects were found, or, that where an adverse effect was noted, the Clinical Review Team found that it had been adequately followed up, and there is no outstanding clinical concern.

Cases Identified for Recall

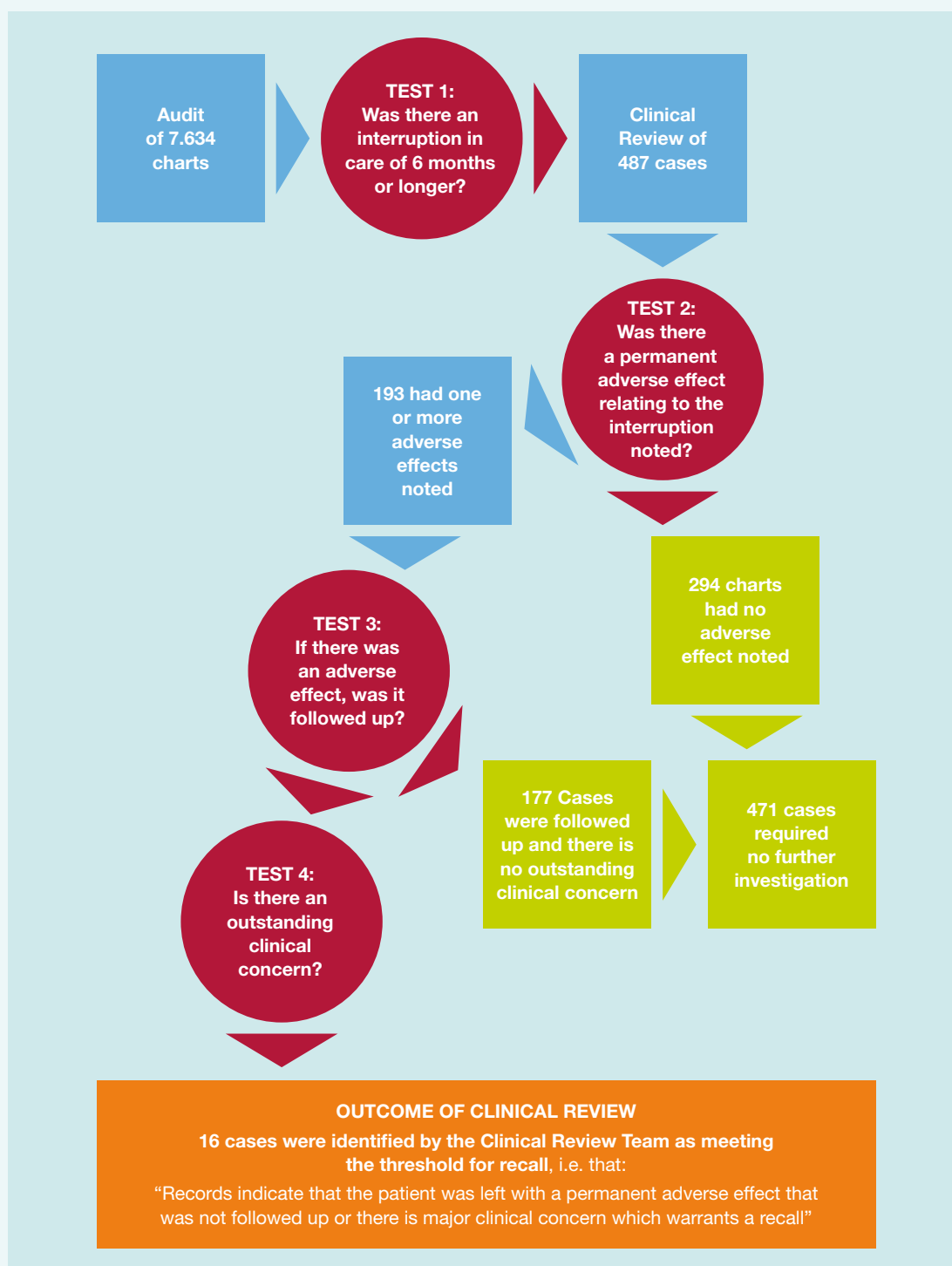
Sixteen cases were identified by the Clinical Review Team as meeting the threshold for recall.

These cases were presented to the SIMT in October 2019. The National Oral Health Lead on behalf of the Clinical Review team presented the findings of their review of 487 cases, including a detailed case report on each of the sixteen cases recommended for recall. The SIMT meeting supported the view of the Clinical Review Team that all sixteen cases met the threshold for recall, i.e.:

“Records indicate that the patient was left with a permanent adverse effect that was not followed up or there is major clinical concern which warrants a recall”

A decision was made by the full SIMT to recall each of the 16 patients. The decisions of the SIMT were unequivocal. Each of the sixteen warranted recall and follow up.

Chart 5.2 Outcome of Clinical Review



There were a number of recurring themes in the 16 cases recommended for recall.

- a) Outstanding clinical concerns.
- b) Orthodontic treatment not commenced.
- c) Incomplete orthodontic treatment plan – further phase(s) of treatment planned but not commenced.
- d) Unfinished orthodontic treatment, i.e. patient wearing appliances.

Table 5.3 Summary of reasons for recall for each of the 16 patients

Case no.	Reason for recall
#1	Incomplete orthodontic treatment plan
#2	Orthodontic treatment not commenced
#3	Orthodontic treatment not commenced
#4	Orthodontic treatment not commenced
#5	Unfinished orthodontic treatment
#6	Outstanding clinical concern
#7	Outstanding clinical concern
#8	Incomplete orthodontic treatment plan
#9	Unfinished orthodontic treatment
#10	Incomplete orthodontic treatment plan
#11	Unfinished orthodontic treatment
#12	Incomplete orthodontic treatment plan
#13	Unfinished orthodontic treatment
#14	Incomplete orthodontic treatment plan
#15	Incomplete orthodontic treatment plan
#16	Outstanding clinical concern

The SIMT concluded that:

Every reasonable effort should be made to contact these patients and undertake full Open Disclosure with each individual. Following disclosure each patient will be offered a clinical assessment and implementation of an appropriate treatment plan if required.

The SIMT anticipated challenges in making contact with the patients given the extended passage of time.

6. Recall & Open Disclosure Process

6.1 Purpose

On completion, the Audit and Clinical Review stages of the Look-back Assessment Process identified potential adverse effects or outstanding clinical concerns for 16 patients that met the threshold for recall. Prior to the commencement of the recall and open disclosure phase of the look back review process, terms of reference including the establishment of a Recall Team were drawn up and approved by the Commissioner (Appendix 2). Under the continued governance of the SIMT, the stages of the recall phase are described below as per the terms of reference and include:

- A. Locate the patients and to ensure all reasonable steps were taken to locate them.
- B. Conduct Open Disclosure in order to inform patients of their inclusion in the audit and the findings in relation to their care.
- C. Offer a dental assessment of the patients in line with the Look-back Assessment Action/Work Plan and the requirements of the HSE Look-back Assessment Process Guideline.
- D. Identify actions to be taken as a result of the findings of the Recall stage of the Look-back Assessment Process.
- E. Implement any remedial actions as appropriate, including individual treatment plans, and communicate any additional actions to be taken by the Commissioner of the Report and to communicate progress and outcomes to the Commissioner.

Due to the passage of time, the SIMT anticipated some challenges in making contact with the patients and initiated a workplan to ensure that all reasonable steps were taken to locate them. The objective was to obtain a current address for each patient.

The task of locating the patients took place between January 2020 and August 2021. It involved undertaking searches of databases held by the HSE's Primary Care Eligibility & Reimbursement Service (PCERS) and the Civil Registration Service (CRS), and those held by the Department of Employment Affairs and Social Protection (DEASP). It also involved making contact with Hospitals and General Practitioners (GPs), as recorded on individual patient files.

Open Disclosure

Open disclosure has been the policy of the HSE since 2013. The Open Disclosure policy applies to patient safety incidents and reflects the primacy of the right of patients to have full knowledge about their healthcare as and when they so wish and to be informed about any failings in that care process, however and whenever they may arise.

Open disclosure is defined in the HSE Interim Open Disclosure Policy (2019) as *an open, consistent, compassionate and timely approach to communicating with patients and, where appropriate, their relevant person following patient safety incidents. It includes expressing regret for what has happened, keeping the patient informed and providing reassurance in relation to on-going care and treatment, learning and the steps being taken by the health services provider to try to prevent a recurrence of the incident.* (HSE 2019).

The Open Disclosure Process of the recall phase was conducted in accordance with HSE Policy. The SIMT ensured that the HSE's obligations in regard to the rights of all patients affected by safety incidents were met and respected, and that all patients were treated with dignity and respect throughout the process.

All stages of the Recall/Open Disclosure phase were carried out in accordance with data protection regulations, cognisant of the rights of individuals to dignity, respect and confidentiality. The onset of the COVID-19 pandemic during the recall phase led to delays in completing the task of locating patients.

The Recall/Open Disclosure phase commenced on 27th November 2020. Public Health guidance in relation to Covid-19 was taken into account when making arrangements for each of the Open Disclosure meetings. Locations that were convenient to the current home location of the patient and which met public health criteria were identified for face to face meetings. Alternatively, it was planned that meetings with patients could take place using phone or digital media, as Public Health needs dictated and in accordance with the patient's wishes.

A detailed account of the searches and processes undertaken to locate the recall patients, and the subsequent open disclosure process that took place with the patients is included in Appendix 6.

6.2 Summary of the Outcome of Open Disclosure Process

The process of locating the addresses for the sixteen patients identified for Recall involved three phases over a period from January 2020 – August 2021. None of the searches undertaken indicated that any of the sixteen patients were since deceased.

Of the Sixteen Patients identified, ten engaged with the Recall Team for Open Disclosure. In this group of patients a range of clinical outcomes emerged during the open disclosure meetings. The clinical outcomes ranged from treatment not commenced, treatment not completed, to treatment completed within the service or completed privately.

Each of the ten patients was offered a dental assessment, as per the terms of reference. As appropriate, treatment plans were initiated in accordance with clinical need and the informed wishes of the patient.

All of the patients that engaged in the Open Disclosure process received an apology on behalf of the HSE.

7. Outcomes, Impacts, Conclusions & Recommendations

7.1 Patient Experience

Impact of delays and interruption of treatment

The HSE would like to highlight the inconvenience, worry, anxiety and difficulties that patients and their families experienced in this service during the period under review due to delays and interruption in their care. This was clearly evidenced in the records reviewed, whereby patients or their guardians voiced dissatisfaction and frustration with little response from the service.

Many families opted out of the system and sought treatment elsewhere. The review team acknowledge that many others could not or did not know how to access alternative care. It was evident from some charts that the request by patients to have their appliances removed was due to frustration in the length of time the treatment was taking.

In the majority of cases where treatment was interrupted, satisfactory outcomes were achieved when treatment was recommenced and completed.

While the results presented from the Clinical Review report only on clinical issues and outcomes, it is clear that many young patients and their parents had poor experiences with the orthodontic service. In many instances, treatment was prolonged for a number of years beyond the original timeframe.

In the course of the Open Disclosure process, it was clear that the frustration, disappointment and dissatisfaction with the service recorded in the orthodontic records over 20 years ago continue to resonate with the patients and their families today.

The impacts of delays and interruptions to treatment on this group of patients and their families were negative and serious. Many of the patients experienced delays and prolonged interruptions in treatment for complex malocclusions that affected their appearance. In a number of instances, patients and their families didn't know if treatment would continue, and assumed that they had aged out of the system.

Some described the personal impact of being left untreated after several years attending the service, while others spoke of the prolonged negative effects of not starting treatment on their sense of wellbeing during their teenage years. In the course of some open disclosure engagements a number of patients spoke of the adverse impact on their lives of delays and interruptions in their care. Some recounted their experience of being bullied, having low self-esteem and a lack of confidence in their appearance.

Facial characteristics and appearance are significant influences on self-perception and self-esteem for children and adolescents. Teasing or bullying of young people due to the appearance of their teeth has been reported in clinical research (Seehra et al, (2011), Scheffel et al, (2014), Smyth, PhD Thesis (2021)); those affected have legitimate expectations that successful orthodontic treatment could have a positive impact on their self-perception and self-esteem.

From the Open Disclosure process, it is evident that these expectations were not met for some patients whose treatment did not commence. For others whose care was interrupted, the prolonged and unacceptable timeframe of their treatment delayed the anticipated benefits.

The members of the Serious Incident Management Team would like to offer its sincere thanks to all patients and their families that met with the HSE during the Open Disclosure process.

7.2 Apology

On behalf of the HSE, we wish to express our deep regret and sincerely apologise to all of those who were let down by our Orthodontic Services and experienced delays and interruption in their care.

7.3 Conclusions

The priority of this look back review was patient safety. The review was undertaken to identify those patients who had an interruption to their orthodontic treatment between the years 1999-2002 and to initiate a recall/open disclosure process for patients that met the clinical threshold for recall. The recall/open disclosure phase included offering a clinical assessment and implementation of treatment plans as required.

As documented, the lookback review took several years to complete due to the complexity of the issue, changes in HSE management structures and a protracted and detailed process of Audit and Clinical Review. This look back review process has revealed that 487 patients had delays or interruptions in their treatment of six months or more, with sixteen of those patients identified for recall.

The process of locating the addresses for the sixteen patients identified for Recall involved three phases over a period from January 2020 – August 2021. Of the Sixteen Patients identified, ten engaged with the Recall Team for Open Disclosure. The Recall Team were unable to locate and engage with six of the patients, despite undertaking extensive searches.

Section 7.1 outlines the impact of delays and interruptions in orthodontic treatment on patients and their families; the conclusions of the SIMT strongly reflect the patient experience as recorded in the records reviewed by the Clinical Review Team and subsequently confirmed by the patients that engaged in the open disclosure process.

In reaching these conclusions, the SIMT has taken account of the examination of the records, its documentation and categorisation of the oral health/orthodontic status, adverse effects and subsequent clinical management of the patients whose care was delayed and interrupted, and the reported experiences of the patients that engaged in open disclosure.

The combination of the review of the records by the Clinical Review Team and the accounts of personal experiences of the patients given to the Recall Team during open disclosure confirm that the period under investigation was characterised by unacceptable delays and interruption of treatment.

The process of reviewing clinical charts involved retrieval of archived records. Paper based records were in use during the period under investigation, which revealed that:

1. During the review process there was limited evidence found of a systematic approach to archiving records. In some instances there appeared to be an ad hoc approach and records were sent for storage when the opportunity arose. From time to time chart filing space within the department was an issue and old, completed, dormant or discharged files would be sent to data storage facilities off site. Charts were randomly placed into storage boxes and sometimes mixed in with study model boxes. The ad hoc practice in the unit was that not all storage box numbers were entered on the patient records. Routine procedures when preparing clinical charts and records for offsite storage is that a catalogue is retained of all charts/records placed in the storage box which has a bar code. Thus a record is retained within the department to facilitate chart retrieval if necessary.
2. The review of the records revealed that charts/clinical records were not routinely signed by the treating clinician. Normal practice at the time was to sign or initial all entries.
3. There was no consistency of filing study models with the patient chart number. Study models were filed separately.

In the majority of cases where treatment was interrupted, satisfactory outcomes were achieved when treatment was recommenced and completed. Many of the patients that experienced adverse effects had these treated satisfactorily in the period following the interruption in their treatment.

However, the look back review of patient records identified a cohort of sixteen patients for recall and open disclosure. In this group of patients a range of clinical outcomes emerged during the open disclosure meetings. The clinical outcomes ranged from treatment not commenced, treatment not completed, to treatment completed within the service or completed privately.

The outcome of the Audit, Clinical Review and Recall/Open Disclosure phases of the look back review have left the SIMT with no doubts about the negative and serious impacts of the delays and interruptions in Orthodontic treatment on the young patients involved and their families. This group of patients and their parents were let down by the service. This was clearly evidenced in the records reviewed, whereby patients or their guardians voiced dissatisfactions and frustrations with little response.

Recommendations arising from the conclusions of the SIMT including the mitigation of risk of harm and/or poor patient experiences and the management of clinical records are presented below.

7.4 Recommendations

In the context of the report's finding and conclusions, the SIMT make the following recommendations to address identified risks and to progress effective care and patient safety within the Orthodontic Service:

7.4.1 Patient Experience

As evidenced in the records reviewed, patients and their guardians voiced dissatisfaction and frustration with the service. Patients and their advocates must have a meaningful voice in relation to planning and delivery of Orthodontic services.

It is recommended that feedback received from ‘Your Service, Your Say’ in relation to the Orthodontic Service including complaints is monitored as part of the Quality & Patient Safety governance arrangements and actions arising implemented.

7.4.2 Clinical Governance

The Lookback Review has revealed historical deficits in the clinical governance structures and process within the DML Orthodontic Service. While the analysis of these deficits was outside the scope of this look back review, the impact on effective patient care and safety must be noted as a risk to patient safety.

It is recommended that the HSE must strengthen Clinical Governance structure, processes and Clinical Leadership in its Orthodontic Services.

7.4.3 Audit

It is recommended that the Clinical Audit Programme for the Orthodontic Service be updated and strengthened to take account of the findings of this Look Back Review and include cyclical reporting of the outcome of treatment provided using the ‘Peer Assessment Review’ (PAR) system and other appropriate audit tools.

7.4.4 Training

- i. It is recommended that all staff involved in dealing with patients should have training and support in managing challenging situations, delays in treatment and complaints.
- ii. It is recommended that all staff should undergo necessary cyclical training in all relevant HSE policies and procedures including records management and retention and the use of email.

7.4.5 Record Management

In response to the findings of the look back review, the following recommendations are made:

- i. The HSE should ensure that the roll out of the electronic national clinical records system to all regional orthodontics services is completed as soon as possible. The Individual Health Identifier (IHI) number should be used on all records created for each patient.
- ii. Full digitalisation is required of all Orthodontic clinical records including clinic visits for assessment, diagnosis, treatment planning and clinical treatment, as well as radiographic images and study models.
- iii. Standardisation of record back-ups and archiving of records should be an integral part of the electronic clinical records management system.

In response to the finding of the impacts of delays and interruptions in treatment, the following recommendations are made:

7.4.6 Treatment interruption alert system

In order to minimise the possibility of undetected adverse effects during orthodontic treatment, an alert system of successive failed appointments should be established, as well as warnings of “in treatment, no appointment scheduled”, repeated cancellations, and an alert threshold of 4 months for those with appliances.

7.4.7 Management and the Clinical Leadership of HSE Orthodontic Services must be cognisant of the potential for adverse effects to arise for patients whose Orthodontic treatment is interrupted for a sustained period of time and take timely and appropriate decisions to mitigate these risks.

In line with the terms of reference of this SIMT, the report including its recommendations will be presented to the Commissioner of the look back review.

8. Appendices

Appendix 1: Terms of Reference – Look-Back Review Process 50971

Introduction

These are the terms of reference for the Look-back Review Process commissioned by the National Director Community Operations into a statement of concern made in 2012 regards an orthodontic service serving the Greater Dublin Area between 1999 and 2002. The potential hazard in this case was interruption to or delay in orthodontic treatment.

Purpose

The purpose of this Look-back Review Process is to identify anyone who has potentially been exposed to the hazard detailed above and to identify, if possible, if any of those exposed have been harmed in order to identify how to take care of them.

A Look-back Review Process will usually consist of three distinct stages:

- The Preliminary Risk Assessment Stage
- The Audit Stage
- The Recall Stage

In this case the Look Back Process is being put in place to provide governance from the point at which the audit required is complete. This is accepted to be unusual however it is the best option available to conclude the management of the case – the only other option being to recommence audit activity which has been on-going since 2015. The Audit Stage is complete and will report to the first meeting of the SIMT. The SIMT will make recommendations to the Senior Accountable Officer on the requirement for open disclosure and/or recall. If a recall is required, the SIMT will oversee this on behalf of the SAO. A recall if required will be under a specific terms of reference to be defined by the SIMT as per the Look Back Review Policy (2015) attached.

The Safety Incident Management Team includes:

- Chair JP Nolan, Head of Quality & Patient Safety
- Siobhan McArdle, Head of Operations Primary Care
- Dr Nader Farvardin, Assistant National Oral Health Lead
- Dr Joseph Green, National Oral Health Lead – Operations
- Michelle Geraghty, Project Manager, National Oral Health Office
- Dr Myra Herlihy, Assistant National Oral Health Lead
- Ann O'Shea, Chief Officer Dublin, South, Kildare, West Wicklow, Community Healthcare Organisation

If experts external to the HSE are required to support any stage of this process, this will be discussed with the Look-back Review Commissioner who will make a decision in relation to the requirement for external experts. These may include legal, clinical etc.

Scope of the Look-back Review Process

The time frame of the Look-back Review Process will be 1999-2002

Please note:

- The “*time frame*” in question here is the “*scope in time*” that was considered appropriate for the Look-back Review Process.
- The timeframe as required is the shortest sufficient period of time to ensure the purposes of the Look-back Review Process as outlined will be achieved.
- The final timeframe will be stipulated and adhered to unless good and valid reasons for extending this timeframe become apparent at any stage of the Look-back Review Process.

Immediate Safety Concerns

Should immediate safety concerns arise during any stage of the Look-back Review Process the SIMT Chair will alert the Look-back Review Commissioner (SAO) who will ensure that appropriate actions are implemented within the shortest time frame possible.

Look-back Review Process Methodology

The Look-back Review Process will follow insofar as possible the methodology as per the Look-back Review Action/Work Plan and the HSE Look-back Review Process Guideline and will be cognisant of the rights of all involved to privacy and confidentiality. This will be from the point of audit onwards in the policy.

Look-back Review Report

Once the Look-back Review process is concluded the Safety Incident Management Team will prepare a detailed and **anonymised** report on the completed Look-back Review Process. This report will include:

- The results of the audit
- The decision as to recall or not and rationale
- The requirement for open disclosure
- The results/findings of the recall stage if required
- Actions taken to date to address findings of audit and/or recall
- Further recommended actions to address findings

As per the HSE incident Management Framework 2018 review reports are not routinely published. No guarantee can be given by the HSE however that information received as part of a look-back review process will be fully protected from legal discovery and/or disclosure.

Recommendations and Implementation

The report, when finalised, will be presented to the Commissioner (SAO) of the Look-back Review Process. The identification of learning and recommended changes to practice and procedures locally and systemically will be included in the Look-back Review Process Report.

The Commissioner of the Look-back Review Process will ensure that local managers responsible for the services included in the Look-back Review Process implement the recommendations of the Look-back Review Process.

The Commissioner will also communicate nationally applicable recommendations to the relevant National Directors for national implementation.

Communication Strategy for the Look-back Review Process

A communication strategy will be determined. If a decision to either open disclose or recall is made a patient and family liaison person will be named as part of the recall team under the recall terms of reference. If required based on the decision following consideration of the audit report the recall terms of reference will also consider communication with other stakeholders and the media.

Reference

- HSE Safety Incident Management Policy (2014, and any subsequent revisions)
- HSE Guideline for Systems Analysis Investigation of Incidents and Complaints (2015) – HSE Look-back Review Process Guideline (2015)
- HSE Incident Management Framework 2018.

Appendix 2: Terms of Reference – Look Back Assessment 50971 – Recall Phase

Introduction

These are the terms of reference for the Recall Stage of a Look-back Assessment Process commissioned by HSE National Director Community Operations into a statement of concern made in 2012 regarding the treatment of children in the Dublin Mid-Leister Orthodontic Service between 1999 and 2002. The recall and recall team will be governed by the SIMT who oversaw the audit phase with a revised membership for the recall phase as below;

- Chair – JP Nolan Head of Quality & Patient Safety
- Siobhan McArdle, Head of Operations Primary Care (*replaced by TJ Dunford, December 2020*)
- Ann O'Shea, Chief Officer CH0 7, replaced by Mary O'Kelly from April 2022
- Dr Joseph Green, National Oral Health Lead
- Michelle Geraghty, Project Manager, National Oral Health Office
- Louise Keena, Business Manager QPS

Purpose

The audit stage of the Look-back Assessment Process has identified potential adverse effects or outstanding clinical concerns for 16 patients. The purpose of this Recall stage is to:

- Locate the patients and to ensure to all reasonable steps were taken to locate them.
- Conduct Open Disclosure in order to inform patients of their inclusion in the audit and the findings in relation to their care.
- To offer a dental assessment of the patients in line with the Look-back Assessment Action/Work Plan and the requirements of the HSE Look-back Assessment Process Guideline.
- Identify actions to be taken as a result of the findings of the Recall stage of the Look-back Assessment Process.
- Implement any corrective actions as appropriate, including individual treatment plans, and communicate any additional actions to be taken by the Commissioner of the Report and to communicate progress and outcomes to the commissioner.

Scope of this Recall stage

Please note:

- The “*time frame*” in question here is the “*scope in time*” for the Recall Stage that was determined by the findings of the Risk Assessment & Audit Stages and is 1999-2002.
- The final timeframe will be stipulated and adhered to unless good and valid reasons for extending this timeframe become apparent during the recall process.

The Recall Team members

One Recall Team is required for the Recall stage of this Look-back Assessment Process in 1 to 3 locations in Dublin and/or Kildare and/or Wicklow based on the current location of the patients and their preferences. The number of Recall Teams required was determined by the Look-back Assessment Commissioner following the outcome of the Audit stage of the Look-back Assessment Process.

The membership of the Recall team is as follows:

- Dr Joseph Green HSE National Oral Health Lead
- Michelle Geraghty, Project Manager, National Oral Health Office
- Áine Clyne, Quality & Patient Safety Manager, National Community Operations
- Clerical support TBC

Through the Commissioner of the Look-back Assessment, the Recall Team will:

- Be afforded the assistance of all relevant staff (including former staff) and other relevant personnel.
- Have access to all relevant files and records (subject to any necessary consent/data protection requirements including court applications, where necessary).
- Should immediate safety concerns arise, the Recall Team Lead will convey the details of these safety concerns to the Commissioner as soon as possible.

Recall Stage Methodology

The recall stage will follow the methodology as per the Look-back Assessment Action/Work Plan and the HSE Look-back Assessment Process Guideline and will be cognisant of the rights of all involved to privacy and confidentiality in so far as possible.

The Recall stage will commence on **27th November 2020** and will be expected to last for a period of approximately **three months** provided unforeseen circumstances do not arise.

All patients who are contactable will be offered a general dental assessment. The Recall Team will advise the Look-back Assessment Commissioner on the follow-up required, which may include:

- No further action required – patient declines contact and reason given.
- Patient declines contact – No reason given or provided
- No further action required following Open Disclosure – patient declines dental assessment.
- No further action required following general dental assessment – update of patient records and reassurance to patient.
- Referral of patient for general dental treatment plan.
- Referral of patient for orthodontic assessment.
- No further action required following orthodontic assessment.
- Referral of patient for orthodontic treatment plan.

The Recall stage may identify that an incident occurred to a patient during the course of their treatment and care. Any incidents which are identified by the Recall stage (i.e. not identified previously) will be subject to the HSE incident Management Framework.

Once the Recall stage has been completed the Safety Incident Management Team will prepare a detailed and **anonymised** report on the completed Look-back Assessment Process. This report will include:

- The Results/Findings of the Recall stage Actions taken to date to address findings
- Further recommended actions to address findings

The anonymised report may be published. No guarantee can be given by the HSE that information received as part of a look-back assessment process will be fully protected from legal discovery and/or disclosure.

Recommendations and Implementation

The report, when finalised, will be presented to the Commissioner of the Look-back Assessment Process.

The identification of learning and recommended necessary changes to practice and procedures locally and systemically will be included in the Look-back Assessment Process Report.

The Commissioner of the Look-back Assessment Process will ensure that local managers responsible for the services included in the Look-back Assessment Process implement the recommendations of the Look-back Assessment Process.

The Commissioner will also communicate nationally applicable recommendations to the relevant National Directors for national implementation.

Communication Strategy for the Recall stage of the Look-back Assessment Process

A communication strategy will be determined. Michelle Geraghty family liaison person will be appointed for the purpose of communicating information pertaining to the Recall stage to the patients/families.

Reference

- HSE Safety Incident Management Framework (2018)
- HSE Guideline for Systems Analysis Investigation of Incidents and Complaints (2015)
- HSE Look-back Assessment Process Guideline (2015)

Appendix 3: Consent Form during the period of investigation



Bord Slainte an Oirthir
**EASTERN
 HEALTH BOARD**

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REGIONAL ORTHODONTIC DEPARTMENT.

ORTHODONTIC CONSENT FORM

For most patients undergoing orthodontic treatment, significant improvements can be achieved. While the benefits of a pleasing smile and healthy teeth are widely appreciated, orthodontic treatment remains an elective procedure, and before making a decision to undergo treatment the inherent risks and limitations should be considered.

Decalcification of enamel.

This will cause permanent marking of the tooth, and can progress to cavitation of the tooth. It is caused by failure to keep the teeth, gums and appliances clean and can also be caused by a surfeit of sugar in the diet. Loose orthodontic bands should be reported as soon as they are noticed.

Root Resorption.

During orthodontic treatment some minimal root shortening is frequently observed and this is usually of no consequence. A small percentage of patients are prone to considerable shortening which can lead to premature loss of teeth.

Appendix 4: Coding Sheet

COLUMN	DETAILS	CODE
A	Chart number	
B	Name	
C	Not seen: > 6 months, < 12 months > 12 months < 18 months > 18 months	0 1 2
D	Oral Health Status: Good Fair Poor Deleterious	4 5 6 7
E	Orthodontic Status: Active treatment Retention	8 9
F	Adverse effects noted on chart	Y/N
G	Oral Surgery: Exposure of canines Impacted/supernumerary Wisdom teeth Orthognathic	A B C D
H	Additional restorative/surgical: care noted on chart Restorative Surgical	 E F
I	Complaints: In writing By telephone	G H
J	Comments	
K	Box number	
L	Not seen by Consultant: >6 mths < 12 months >12 mths < 18 mths > 18mths	0 1 2

Appendix 5: Key to Recording Clinical Findings

Orthodontic Look back

Key to Excel Template	
1.	TOOTH WEAR – Abnormal Wear or Loss of Tooth Substance – which can be associated with the appliance or to the interruption of orthodontic treatment
2.	TOOTH DECAY – Tooth Decay – note the extent
3.	DECALCIFICATION – Enamel Decalcification – note the extent
4.	PERIO DISEASE – Periodontal Disease – resulting in pocketing and/or crestal bone loss occurring during orthodontic treatment associated with poor oral hygiene
5.	RESORPTION – External Apical Root Resorption (ARR) – radiographic evidence of shortening of the root length
6.	TMD – Temporomandibular Joint Dysfunction (TMD) – persistent TMD
7.	ASPIRATION – Aspiration or Ingestion of Orthodontic Appliances
8.	INJURIES – Patient Injuries from Orthodontic Appliances – other permanent/significant intra or extra oral injury caused by the orthodontic appliance
9.	PAIN – Pain and Discomfort – where a significant issue was noted
10.	OTHER – Other Relevant Clinical Notes
11.	RECALL – the “Threshold” of the decision to recall a patient for clinical examination has been reached – records indicate that the patient was left with a permanent adverse effect that was not followed up.
12.	NO DISC – No Discharge records on patient file

The findings are recorded as Yes or No (Y/N) in each column.

“Records indicate that the patient was left with a permanent adverse effect that was not followed up or there is major clinical concern which warrants a recall”

Appendix 6: Process to Locate Patients, Recall & Invite to Engage in Open Disclosure

A.1 Process to Locate Recall Patients (1)

The contact details available to the SIMT for all of the sixteen patients identified for recall and open disclosure were those of their childhood addresses as recorded on their orthodontic record in the mid to late 1990s. At all stages of the recall phase, the principle of respecting the privacy and confidentiality of those concerned was adhered to in addition to ensuring that all personal information obtained was done so in accordance with data protection regulations.

To begin the process, the following information needed to be ascertained:

- a) Confirmation if any of the sixteen patients were since deceased
- b) Obtain a current address for each of the sixteen patients

For the purpose of contacting patients, the first step taken in this regard by the SIMT was for the Chair to write on 24th January 2020 to the HSE National Director for Data Protection seeking advice and permission to search all relevant data bases held by the HSE for any updated records on the sixteen patients.

On 29th January 2020, The HSE National Director for Data Protection replied and advised the SIMT to request information from the following databases held by the HSE:

1. The data bases of the Primary Care Eligibility and Reimbursement Service (PCERS). The HSE's Primary Care Eligibility & Reimbursement Service (PCERS) is responsible for issuing medical cards and administers the drug refund scheme. Members of the public make applications to the PCERS for medical cards and refunds of drug payments.
2. The data bases of the Civil Registration Service which record all births, deaths and marriages (CRS).

A.1a Initial Primary Care Eligibility and Reimbursement Service (PCERS) Searches

On 14th February 2020, the Chair of the SIMT made a formal written request to the Assistant National Director for PCERS seeking assistance to access the PCERS databases to search for the contact details of the sixteen patients.

On 21st February 2020, The Assistant National Director, PCERS responded by email offering the SIMT the assistance of a PCERS staff member who would be assigned to carry out the searches across multiple systems, i.e., the three databases held by PCERS: National Schemes Viewer (NSV), Oracle (PPSN Information) & Claiming History. Searching across three databases offered the best opportunity to establish the most recent address used by an individual in correspondence with the PCERS

On 5th March 2020, a meeting took place between two members of the SIMT assigned to research the task of locating the recall patients and the PCERS staff member assigned to assist with the search. Hard copies of the childhood details held on record for each of the sixteen patients identified for recall and open disclosure were provided to PCERS to facilitate the searches. The PCERS staff member was made aware of the confidential nature of this request and of the necessity to use all reasonable methods to make contact with the patients.

Initial PCERS Search

The following information was provided to PCERS: name, address, date of birth and telephone number from the orthodontic records. During the period under review a Personal Public Services Number (PPSN) was not routinely requested by the Orthodontic Department. PPSN is a critical requirement in searching PCERS databases.

For each patient the PCERS researcher followed the protocol set out below:

1. To identify the patient's PPSN, an initial search was conducted using name, address, date of birth (DOB) in the **National Schemes Viewer**:
 - If this search was *successful* a PPSN was identified and then further searches of claims history were undertaken – see point 3 below.
 - If this search was *unsuccessful* for PPSN, via name, address and DOB, then the second search was conducted to try to establish current address – see point 2 below.
2. Second search into browser **Oracle** was conducted, searching with address, name, DOB and PPSN where available –
 - If this search was *successful*, the researcher was able to search the Claiming History – see point 3 below.
 - If this search was *unsuccessful*, the researcher was unable to search the Claiming History of the patient.
3. Third search when PPSN was available was of the person's **claims history** in the General Medical Scheme (GMS) and the Drugs Refund Scheme.

Outcome of Initial PCERS Search

Secure email was used throughout all correspondence between PCERS and one nominated SIMT member. On 9th March 2020, the PCERS results of the search were returned. The search yielded positive current matches for the addresses for two of the recall patients. The outcome of the PCERS search confirmed that the childhood addresses for these two patients remained current on the PCERS records. There was no updated information for the remaining fourteen (14) childhood addresses and no information from the PCERS search to indicate that any of the sixteen patients were deceased. Therefore, at the end of the first PCERS search:

- The sixteen childhood addresses remained with two positively matching from recent PCERS history.
- There was no information from the PCERS search to indicate that any of the sixteen patients were deceased.

COVID-19

Members of SIMT were redeployed during the unprecedented COVID-19 emergency from mid-March until May 2020 and therefore the SIMT was unavailable to convene during this period which temporarily slowed down the recall process. There was continued commitment from the SIMT that every reasonable effort should be taken to contact these patients and that all methods of acquiring up to date information was recorded. Therefore, the task of locating current contact details for the sixteen patients continued during this period.

A.1b Initial Civil Registration Service (CRS) Search

The next step in the search process was to seek permission to access the HSE's Civil Registration Service's (CRS) database.

On 28th May 2020, a response was received from the Head of Service, Primary Care with responsibility for CRS giving permission and advising to contact the Superintendent Registrar directly regarding CRS database search.

On 8th June 2020, the National Oral Health Lead (NOHL) who was a member of SIMT wrote to the Superintendent Registrar seeking assistance from CRS with acquiring up to date location details for the sixteen patients identified for recall and open disclosure, stressing the confidential nature of request. In the interests of confidentiality, encrypted details of the information available to the SIMT for each patient were sent separately.

Outcome of Initial CRS search

On 9th June 2020, Superintendent Registrar, CRS responded to the National Oral Health Lead that a search had been completed on The Civil Registration Service system using patient details, name, address and DOB. The outcome of the search confirmed that:

- a) All births were found but 2 patient records had a different DOB on the CRS system.
- b) Marriage details were found for 4 patients and the addresses at the time of marriage were recorded and returned. Three of the patients identified as married were female and one was a male patient.

Second PCERS Search

On 29th June 2020, following SIMT approval on 25th June, a request was made to PCERS to carry out a further search in relation to the two different DOBs for the two patients obtained from the CRS search.

On 30th June 2020, PCERS reported back through secure email that following a search by name, date of birth supplied by CRS and address, there was confirmation for name and new date of birth for both patients, but that the addresses held in PCERS did not match the information supplied by CRS.

The outcome of second PCERS search therefore did not produce a current address and/or an address that differed from the childhood address for those two patients.

Second CRS Search

On 16th July 2020, a further attempt to locate current addresses took place using the Civil Registration Service system. The SIMT nominated research member made a request for the surnames of each of the spouses for the three female patients who were identified as having been married in the first CRS search that took place earlier on 9th June 2020.

Outcome of second CRS search: Confirmation of the spouse's surnames for the three female patients was received via encrypted email on the same day.

Third PCERS Search

On 16th July, the SIMT nominated research member requested a further PCERS search for four of the patients two of which were not matched with a PPS number in the first PCERS search.

On 17th July 2020, the nominated research member contacted PCERS again with the addition of the surnames of the spouses for two of the female patients identified as married in CRS search in order to facilitate the search.

On 23rd July 2020, PCERS returned encrypted search results.

The outcome of this third PCERS search which included the surnames of the spouses of two of the female patients **did not yield any further contact information** in regard to identifying either a current address or an address that was different than the childhood address for both of these female patients.

A.1c Acute & Specialist Hospital Searches

The Orthodontic charts of three of the sixteen patients also contained a hospital reference number: two related to an Acute Hospital and one for a Specialist Hospital. Again, in the interest of making all reasonable efforts to locate the patients identified for recall and being cognisant of data protection, the Chair of the SIMT wrote to both the Specialist Hospital and the Acute Hospital on 1st and 4th September 2020 respectively seeking assistance with confirmation of contact details. These two requests were made following legal advice and in accordance with GDPR, article 9.2H.

On 11th September 2020, a reply was received from the Acute Hospital confirming a match for one of the patient's demographics regarding hospital number and the childhood contact details. In regard to the second patient, the Acute Hospital confirmed that there was no match with the hospital number supplied by the SIMT from the Orthodontic Chart but that the demographic and contact details matched with a different patient record number held by the Hospital.

Outcome of Acute & Specialist Hospital Search

In summary, the Acute Hospital search confirmed one patient's contact details matched the orthodontic record supplied by the SIMT and that the second patient's childhood contact details were confirmed with the exception of the Hospital number.

On 17th September 2020, a positive response was received from the Specialist Hospital confirming demographic and contact details supplied by the SIMT for the patient whose orthodontic chart contained reference to a specialist hospital number. The contact details did not differ from the childhood address identified in Orthodontic Chart.

A summary of the outcomes of these searches that took place between January & September 2020 is outlined below.

Table A.1

Outcome of Database Searches to Locate Recall Patients, January-September 2020

Initial Primary Care Eligibility & Reimbursement Service (PCERS) Search				
Outcome				
2 positive matches with childhood addresses		#12		#15
No PPSN for 2 patients		#9		#16
No information to indicate that any of the sixteen patients were deceased.				
Initial & 2nd Civil Registration Service (CRS) Search				
2 separate searches undertaken				
1st Search Outcome				
All births were found but 2 records had a different DOB on the CRS system	#8	#16		
Marriage details were found for 4 patients (three female and one male) and the addresses at the time of marriage were recorded and returned	#1	#8	#12	#16
2nd Search Outcome				
Confirmation of the spouse's surnames for the three female patients identified as married	#1	#8	#16	
Second PCERS Search				
Search in relation to 2 different DOBs for the two patients obtained from the CRS search				
Outcome				
No further contact information was found for these two patients		#8		#16
Third PCERS Search				
Using surnames of the spouses for two female patients identified as married in CRS search				
Outcome				
No further contact information to identify either a current address or an address that was different than the childhood address for both of these Female patients		#1		#8

Acute Hospital Search

Outcome

2 patients' childhood contact details matched with Hospital records with the exception of the Hospital number for one patient (#2) #2 #5

Specialist Hospital Search

Outcome

One (1) patient contact details did not differ from the childhood address identified in Orthodontic Chart #6

Summary Outcomes of PCERS, CRS & Hospital Database Searches to confirm addresses of Recall Patients, January-September 2020

- Updated addresses were found for two (2) of the patients in the searches
- No updates to childhood addresses for fourteen (14) of the patients following searches
- No information emerged to indicate that any of the sixteen (16) patients were deceased

A.2 Preparation for Open Disclosure & Recall Meetings

Arrangements for Open Disclosure and Recall Meetings

On 17th September 2020, the SIMT Meeting recorded a general consensus that the efforts taken to locate the contact details of the sixteen patients identified for recall were reasonable and that the recall and open disclosure stage could proceed. The SIMT recommended to the National Director that recall of the 16 patients concerned be commenced at this stage and this was agreed. A Work plan was developed in accordance with the recall terms of reference with the aim of holding open disclosure meetings before the end of year 2020 and to arrange for any dental reviews required early in 2021.

The first step in the work plan was to prepare to make contact with the sixteen patients and to offer open disclosure meetings. The recall phase was targeted to commence in the week of **27th November 2020** with an expected duration of approximately **three months** provided unforeseen circumstances did not arise. Steps taken in preparation included:

Managing Data

- A SIMT Member was assigned to maintain an encrypted spreadsheet with a unique identification code, the demographic details available from each of the patients' orthodontic chart and the most recent addresses available for each of the individual patients as per the outcome of all searches carried out to date. This was to ensure that all information gathered was stored in accordance with data protection regulations.

Designated Person for Open Disclosure

- Assignment of a Designated Person for the Open Disclosure process, ie a person to maintain contact and to liaise with the patient/relevant person and the recall team during the process.

Advocacy Services

- Arrangements were put in place for the provision of Advocacy Services to support the process of making contact with the sixteen patients. On 30th November 2020, the Chair of the SIMT made contact with a senior representative from SAGE, Advocacy Agency. Permission was given by SAGE to share both phone and email contacts with any of the patients who so wished to avail of the advocacy service.

Communications

- The content of letters to issue to each of the patients inviting them to make contact with the Recall Team were agreed by the SIMT.
- The implementation of a communication plan including preparation and provision of a press statement.
- On 20th October 2020, a meeting was held by the Chair of the SIMT with the National Oral Health Lead and a nominee from National Communications Team where agreement was made on the content of anticipated questions from members of the public, should they arise and prepared responses for HSELive.
- A telephone verification process to confirm the identity of caller was developed and put in place.

Recall Team

In order to carry out the recall and open disclosure process, the SIMT assigned members to a 'Recall Team'. A list of membership is included in the full Recall Terms of Reference, Appendix 2. The role of the recall team was to liaise and to maintain contact with each patient to the end of the recall process, which included:

- Conducting the open disclosure meetings at which each patient would be informed of why they were included in the audit, the findings in relation to their care, and be offered an apology on behalf of the HSE for the delays and interruptions in their treatment.
- Offering a dental assessment to the patient in line with the Look-back Assessment action/work plan and the requirements of the *HSE Look-back Assessment Process Guideline*.
- Identifying actions to be taken as a result of the findings of the Recall stage of the Look-back assessment process for each of the patients.
- Implementing any corrective actions as appropriate, including individual treatment plans, and communicating any additional actions to be taken by the Commissioner of the Report alongside communicating progress and outcomes to the Commission.

A.3 Invitation to Open Disclosure & Recall Meetings (1)

Making Contact for Open Disclosure & Recall Meetings

The letter inviting the patients to make contact with the Recall Team was prepared and approved by SIMT and issued by registered post on 27th November 2020 to each of the sixteen patients at the available addresses, (Appendix 6). The registered Letters issued were marked as '*Private & Confidential*' with a return address to the National Oral Health Office. The letters contained details of a dedicated phone line established for these patients to make contact with the HSE during working hours, Monday-Friday. This was operated by the Designated Person who on receiving phone contact, arranged for the senior dental clinician from the Recall Team to return a call, answer questions and proceed with setting up the open disclosure meetings, as required.

Covid-19

Public health guidance was taken into account in making arrangements for Open Disclosure meetings. Locations that were convenient to the current home location of the patient and which met public health criteria were identified for face to face meetings. Alternatively, it was planned that meetings with patients could take place using phone or digital media, as Public Health needs dictated and in accordance with the patient's wishes.

Table: A.3

Response to invitations to Open Disclosure & Recall Meetings				
Sixteen Initial letters issued to the patients, November 2020				
Five letters were delivered and received	<ul style="list-style-type: none">Patients made contact with the HSE via the dedicated phone line	#3	#4	
		#6	#10	
		#13		
Seven Letters delivered with no response	<ul style="list-style-type: none">There was no contact forthcoming from seven of the recipients of the letters delivered	#1	#2	
		#7	#12	
	<ul style="list-style-type: none">Follow up steps to confirm the identity of the signatories of those who signed for the letters proved inconclusive	#14	#15	
		#16		
Four letters were returned to the HSE as undelivered to the named recipients	<ul style="list-style-type: none">Three letters were returned to the National Oral Health OfficeOne letter was returned to the local Post Office for collection	#5	#8	
		#9	#11	
Outcome				
5 Patients	<ul style="list-style-type: none">made contact with HSE			
11 Patients	<ul style="list-style-type: none">No contact received			

A.4 Process to Locate Recall Patients (2)

A.4a Department of Employment Affairs & Social Protection (DEASP) Search

The SIMT continued to pursue current addresses and to make contact with the **eleven remaining patients** identified for recall within data protection regulations.

On 13th January 2021, the SIMT noted approval for letter to be sent to the Department of Health requesting permission for the Department of Employment Affairs & Social Protection (DEASP) to carry out a search for the contact details of the **eleven** patients who had not yet responded to initial open disclosure letters. This included the four returned registered letters and the seven letters from which no reply was received by the HSE.

On 19th January 2021, SIMT noted approval via the Department of Health to make a search request to the Department of Employment Affairs & Social Protection (DEASP). The DEASP search results yielded the following outcomes:

Table A.4

Outcome of DEASP Database Search for the addresses of 11 patients			
5 patients	Addresses used in letter of 27th November 2020 were confirmed	#1 #12 #15	#2 #14
4 patients	New addresses identified (including a different house number for one patient)	#5 #8	#7 #11
2 patients	No new addresses identified & No PPSN available	#9	#16

A.5 Invitation to Open Disclosure & Recall Meetings (2)

Taking account of the DEASP search, the SIMT took the following actions:

1. On 23rd February 2021, second letters were sent by registered post to 5 patients whose addresses had been confirmed by DEASP (Appendix 7). The letters advised the patients that the quality assurance, recall process was to be finalised one month after the date of the 2nd letter. Confirmation was received from An Post that all letters were delivered.
2. On 5th March 2021, second letters were sent via registered post to the 4 different addresses identified by the DEASP search. All were for those whose initial letters were returned. (Appendix 8)
3. In one case, DEASP identified an address with a different house number to that recorded on the front of the patient's orthodontic chart. The patient's orthodontic chart included addresses with two different house numbers.

No further correspondence was sent to the 2 patients where no PPSN number was identified nor any new address or confirmation of address was found arising from DEASP search.

Table A.5

Summary Response to Invitation to Open Disclosure & Recall Meetings (2)			
Outcome of 5 second letters sent on 23rd February to those addresses that had been confirmed by DEASP:			
2 letter	responded	#2	#12
3 letters	no response	#1 #15	#14
Outcome of 4 second letters that were sent on 5th March to the 4 different addresses identified by the DEASP search:			
3 Letters	3 patients made contact with HSE via dedicated phone line	#7 #11	#8
1 letter	returned undelivered	#5	

Summary Response to Invitation to Open Disclosure & Recall Meetings (2)

No New addresses identified by DEASP for 2 Patients

2 patients	No further correspondence sent (no PPSN number was confirmed nor any new or confirmation of address arising from DEASP search)	#9	#16
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Outcome from actions taken following DEASP search

5 Patients	Made Contact with HSE via dedicated phone line	#2	#7
		#8	#11
		#12	
6 Patients	No contact received by HSE	#1	#5
		#9	#14
		#15	#16

A.6 Process to Locate Recall Patients (3)

A.6a Childhood General Practitioner (GP) Search

On 6th May 2021, The SIMT agreed that in the interest of taking all reasonable steps to make contact with the six outstanding recall patients, that correspondence would be sent to the childhood GP contacts documented in five of these remaining patients' files, seeking assistance in regard to updated addresses for the patients. There were no GP details in the chart of one patient, to whom two letters had previously been sent to and returned undelivered. The outcome of this GP search which took place in June 2021 (letters sent 18-19th June 2021) resulted in four of the five GP practices responding of which three of the GPs were in a position to offer positive assistance. The fourth replied that the GP as listed on the patient's file was now deceased and they were unable to assist. This patient's file advised that this same patient also attended a Consultant in a Dublin Hospital.

On 21st July 2021, at a further SIMT meeting, agreement was made to seek assistance from the Hospital Consultant in the interest of locating and making contact with this recall patient.

A.6b Further Civil Registration Search (CRS)

In the first instance, the SIMT agreed that contact should be made with the Civil Registration Service (CRS) for a further update on this patient's status prior to making contact with the Hospital Consultant.

On 27th July, the SIMT received a reply stating that CRS had no death notification for the patient.

A.6c Hospital Consultant Search

On 11th August 2021, the Chair of the SIMT wrote to the Hospital Consultant.

On 13th August 2021, a response was received that confirmed that the Patient had last attended the Hospital on 24th February 2021 and that their childhood address remained unchanged.

Table A.6

Summary of Childhood GP Search		
Seeking assistance in locating Recall Patients – Letters sent to Childhood GPs, 18-19th June 2021		
Patient	Outcome	Follow Up SIMT Actions
#1	No GP Response to date.	
#5	No GP details in Orthodontic Chart	
#9	GP offered assistance.	NOHL made phone contact with GP Practice who stated that Patient had never attended GP practice and supplied updated address on GP file. 22nd July NOHL wrote to Patient at updated address. Outcome: No response from Patient.
#14	Childhood GP, RIP. New GP Practice offered assistance. Responded last contact with Patient was 2005. Outcome: Yielded no additional information. Confirmed childhood address as last contact detail on GP file.	
#15	23/07/21: Childhood GP, RIP. It was noted on Patient's orthodontic chart that Patient had also attended Hospital Consultant.	On 11th August 2021, the Chair of the SIMT wrote to the Hospital Consultant. Outcome: A Response was received on 13th August 2021 that confirmed that the Patient had last attended the Hospital on 24th February 2021 and that they maintained the same childhood address. Therefore, no additional information yielded.
#16	26/07/21: Outcome: Confirmed Childhood GP now retired. New GP practice responded they were not familiar with patient. File recorded last GP attendance 2001. No additional information yielded.	

The GP search and associated follow up actions did not yield any additional information that enabled the Recall Team to make further efforts to establish contact with any patients within this cohort. In light of this, a decision was taken by the SIMT that all reasonable efforts had been made to contact the remaining six (6) patients identified for recall.

Therefore, no further open disclosure meetings were initiated after the final phase of searches made to locate addresses for the remaining patients.

Appendix 7: Letter of invite to Patients from Recall Team, 27.11.2020



Oifig Náisúinta Sláinte Béal
Feidhmeannacht na Seirbhíse Sláinte
31-33 Sráid Caitríona
Luimneach

National Oral Health Office
Health Service Executive
31-33 Catherine Street
Limerick

Private & Confidential

Re: Orthodontic treatment at St James Hospital

Dear,

I am writing to you on behalf of the HSE. We would like to talk to you about the orthodontic treatment you received in St. James Hospital between XXXX and XXXX. We have reviewed the treatment provided to you as part of a quality assurance process and our clinical team would like to meet with you to discuss the treatment received and to ensure that you have no concerns in this regard.

Please be assured that this is not an urgent medical matter and there is no reason for you to be concerned, but we would like to speak with you about your care and hope you would be willing to speak with us.

I would like to arrange an appointment for you to meet with us to discuss the treatment you received, and ask that you call xxxx from the National Oral Health Office on xxxxxxxxxxxx. Please ring between 9am and 5pm, Mon-Friday. A suitable date for a meeting in the Dublin area will be arranged. This may be on the phone or by video due to COVID 19.

I apologise for any anxiety this might cause but wish to reassure you that this is a precautionary measure to ensure your care was of the highest possible standard.

If you decide to speak with us, you will be assigned a named contact person and we can have an initial discussion when you make contact.

Looking forward to hearing from you.

Yours sincerely

Appendix 8: Letter of invite to Patients from Recall Team, 23.02.2021



Oifig Náisúinta Sláinte Béal
Feidhmeannacht na Seirbhíse Sláinte
31-33 Sráid Caitriona
Luimneach

National Oral Health Office
Health Service Executive
31-33 Catherine Street
Limerick

Private & Confidential

Re: Orthodontic treatment at Regional Orthodontic Department

Dear,

I first wrote to you in XX XXXX about a HSE quality assurance process relating to your orthodontic treatment at the Regional Orthodontic Department at St James Hospital between XXXX and XXXX.

In this letter that was delivered on XX XX XXXX, I stated that we had reviewed the records of your treatment as part of a quality assurance process and our clinical team would like to meet with you to discuss the treatment received and to ensure that you have no concerns in this regard.

Please be assured that this is not an urgent medical matter and there is no reason for you to be concerned, but we would like to speak with you about your care and hope you would be willing to speak with us.

I wish to advise that the HSE quality assurance process is now reaching its final stages and will close on XX XX XXXX. Our records show that we have yet to hear from you. Should you wish to speak with the HSE, please contact xxxxxxxxxx and I will return your call, or by email to xxxxxx before XX XX XXXX.

Yours sincerely

Appendix 9: Letter of invite to Patients from Recall Team, 05.03.2021

Oifig Náisúinta Sláinte Béal
Feidhmeannacht na Seirbhíse Sláinte
31-33 Sráid Caitriona
Luimneach

National Oral Health Office
Health Service Executive
31-33 Catherine Street
Limerick

Private & Confidential

Dear,

I am writing to you on behalf of the HSE. We would like to talk to you about the orthodontic treatment you received in St. James Hospital between XXXX and XXXX. We have reviewed the treatment provided to you as part of a quality assurance process and our clinical team would like to meet with you to discuss the treatment received and to ensure that you have no concerns in this regard.

In seeking to contact you, the HSE has previously written to you at your childhood address. When that letter was returned, the HSE requested your current address for correspondence from the Department of Employment Affairs and Social Protection and it was provided in accordance with data protection law.

Please be assured that this is not an urgent medical matter and there is no reason for you to be concerned, but we would like to speak with you about your care and hope you would be willing to speak with us.

I would like to arrange an appointment for you to meet with us to discuss the treatment you received, and ask that you call me at the National Oral Health Office on xxxxxxxxxx. Please ring between 9am and 5pm, Mon-Friday. A suitable date for a meeting in the Dublin area will be arranged. This may be on the phone or by video due to COVID 19 restrictions. Alternatively you can email me at xxxxxxxxxx.

I apologise for any anxiety this might cause but wish to reassure you that this is a precautionary measure to ensure your care was of the highest possible standard.

If you decide to speak with us, you will be assigned a named contact person and we can have an initial discussion when you make contact.

Looking forward to hearing from you.

Yours sincerely

Appendix 10: Glossary of Terms & Abbreviations

Glossary of terms	Description
Appliance	Orthodontic device used to move or retain position of teeth, can be fixed to the teeth or removable
Arch wire	A special U-shaped metallic wire used for proper straightening and movement of the teeth; attaches to orthodontic brackets to guide tooth movement
Band	A bracket for a molar or back tooth; fits around the entire tooth
Bonding	The process by which brackets and bands are attached to the teeth by an adhesive.
Bracket	Piece of shaped metal or ceramic that is fixed to each tooth; that allows and controls the movement of each tooth
Cavitation	Hole created in a tooth due to decay
Decalcification	White spots on teeth
Debond	The removal of bonded orthodontic brackets
Designated Support Person	This person is a contact point for the service user/relevant person(s) impacted by an incident.
Gingiva	The tissue that surrounds the teeth; also known as “gums”.
Gingival conditions	Conditions affecting the gums
Keogh system	IT system used to file records
Look-back process	Review where a number of people may have been exposed to a specific hazard in order to identify if any of those exposed have been harmed and how to take care of them. A Process consisting of three key stages: Preliminary Risk Assessment, Audit and Recall.
Malocclusion	A deviation from normal when the teeth are in occlusion (biting together).
Modules	Small elastic rings used to hold the arch wire onto each bracket
Open Disclosure	Open disclosure is defined as an open, consistent, compassionate and timely approach to communicating with patients and, where appropriate, their relevant person following patient safety incidents. It includes expressing regret for what has happened, keeping the patient informed and providing reassurance in relation to on-going care and treatment, learning and the steps being taken by the health services provider to try to prevent a recurrence of the incident (HSE 2019)

Glossary of terms	Description
Orthodontics	The specialty of dentistry that is concerned with facial growth, the development of the occlusion and dentition as well as with the diagnosis, interception and treatment of occlusal anomalies (Littlewood and Mitchell, 2019).
Orthodontic treatment	The diagnosis, prevention and correction of mal-positioned teeth and jaws, usually with orthodontic appliances
Orthognathic treatment	Surgery to correct discrepancy in the size and/or position of the jaws
Orthotrac	An orthodontic practice-management software
PAR	Peer Assessment Rating
Periodontal	The tissue that surrounds and supports the teeth
Resorption	(see Root resorption)
Retainer	An appliance used to stabilise teeth in their new positions after orthodontic treatment
Retention phase	Period after active orthodontic treatment to hold and stabilise teeth in the new position
Root canal treatment	A procedure to remove the nerve and pulp inside of the tooth and root/s with subsequent cleaning and sealing of the spaces.
Root resorption	Progressive loss of tooth substance on roots of teeth which can result in the shortening of the roots
Serious Incident Management Team (SIMT)	A Serious Incident Management Team is a group whose role is to oversee the management of all serious incidents relating to the service
Study Models	Plaster casts of the teeth
Temporomandibular dysfunction	Problems with the joints between the mandible and the skull
Tooth Decay	A breakdown of teeth due to acids made by bacteria
Tooth wear	Refers to loss of tooth substance by means other than tooth decay

Abbreviations	
CRS	The HSE Civil Registration Service registers all births, deaths and marriages in Ireland.
DEASP	Department of Employment Affairs & Social Protection The Department of Social Protection is a department of the Government of Ireland, tasked with administering Ireland's social welfare system. It oversees the provision of income support and other social services. It is led by the Minister for Social Protection who is assisted by two Ministers of State.
DML	Dublin Mid-Leinster
DNA	(patient) Did Not Attend
GMS	The Primary Care Eligibility & Reimbursement Service (PCRS) is part of the HSE, and is responsible for making payments to healthcare professionals, like GPs, dentists and pharmacists, for the free or reduced costs services they provide to the public medical card holders)
HSE	Health Service Executive
IHI	Individual Health Identifier
PCERS	The Primary Care Eligibility & Reimbursement Service (PCRS) is part of the HSE, and is responsible for making payments to healthcare professionals, like GPs, dentists and pharmacists, for the free or reduced costs services they provide to the public.
PPSN	The Personal Public Service Number is an identifier issued by the Client Identity Services section of the Department of Social Protection, on behalf of the Minister for Social Protection in Ireland.



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Publication Date: April 2022