



CED ANNUAL REPORT ON UNDESIRABLE EFFECTS OF TOOTH WHITENING PRODUCTS

**SECOND REPORT
1 November 2013 to 31 October 2014**

The content of this report represents the views of the CED and is its sole responsibility; it can in no way be taken to reflect the views of the European Commission or any other body of the EU.

I – Introduction

This is the second report prepared under an agreement signed between the CED and the European Commission on 31 March 2010 in the framework of the future regulation on the use of tooth whitening or bleaching products (TWP)s¹. The first report covered the period from 31 October 2012 to 31 October 2013 and is available [here](#)².

The agreement was signed to support the ongoing availability of tooth whitening products on EU market, to ensure that these products are not directly available to the consumer and that, for each cycle of use, the first use is limited to dental practitioners, as defined under Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications, or under their direct supervision if an equivalent level of safety is ensured.

II – Methodology

The report was prepared based on the reporting incidents received from dentists between 1 November 2013 and 31 October 2014 who have themselves observed undesirable effects caused by tooth whitening products or from dentists whose patients have reported to them undesirable effects caused by tooth whitening products, with concentrations of hydrogen peroxide between 0.1% and 6% and of carbamide peroxide between 0.3% and 16.62%.

In order to implement the annual reporting activity, the CED prepared a second questionnaire for dentists to report undesirable effects (see Annex I – Second Survey on Undesirable Effects).

The questionnaire was made available online in www.surveymshare.com between 1 November 2013 and 31 October 2014 through the link <http://www.surveymshare.com/s/AYA6A3D>. The survey could only be answered online and the survey's link was merely provided to CED Members in order to avoid false reporting. As the answers are anonymous there was no possibility to check the authenticity of the replies.

The survey was advertised on the CED website (please see [here](#)³).

The CED informed its members about the survey encouraging them to distribute the questionnaire among their members and non-members through the CED mailing on 19 December 2013, a written reminder on 29 August 2014 and an oral reminder during the CED General Meeting on 23-24 May 2014.

The CED requested its members to:

- i. make the link available to dentists only in order to avoid false reporting. In case of replies on paper, to complete the form directly online or send the reply to the CED (ced@eudental.eu);
- ii. translate the questionnaire in their national language/s;

¹Tooth whitening or bleaching products are currently regulated by Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. This Regulation repealed Council Directive 2011/84/EU of 20 September 2011 amending Directive 76/768/EEC, concerning cosmetic products, for the purpose of adapting Annex III thereto to technical progress. The latest consolidated version of Regulation (EC) No 1223/2009 is available at <http://eur-lex.europa.eu/legal-content/EN/AUTO/?uri=CELEX:02009R1223-20150416>.

² <http://www.eudental.eu/component/attachments/attachments.html?task=download&id=1582>

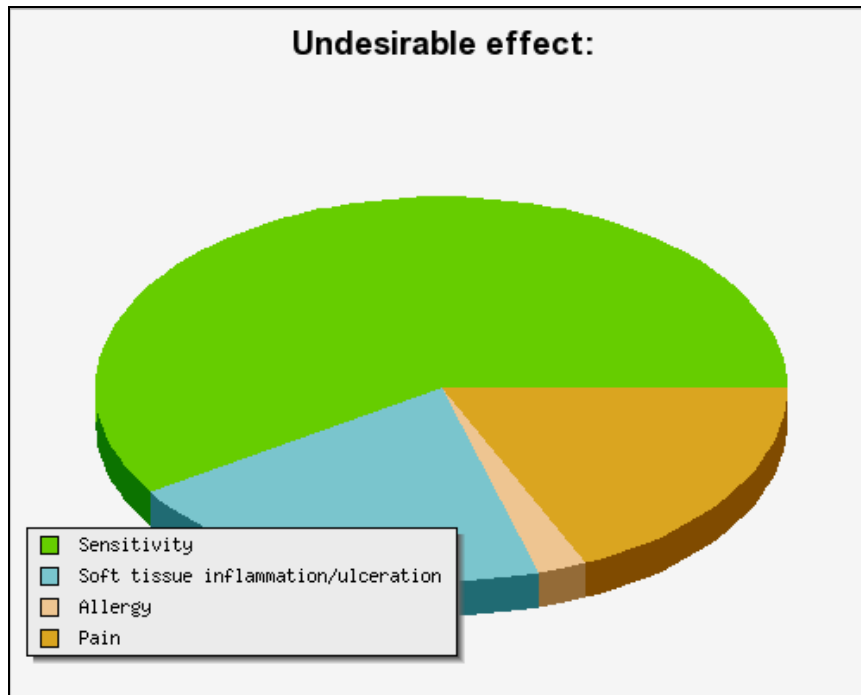
³ <http://www.eudental.eu/library/surveys.html>

- iii. advertise the link in their newsletter, journal, website (member's only part), other relevant national stakeholders (e.g. ministries, patients' organisations, dental schools), etc., encouraging them to reply;
- iv. use the CED logo in their national campaign for this specific survey if appropriate; and
- v. inform and reassure their members that the survey was anonymous and that it is generally assumed that any undesirable effects result from the product itself and not from dentists' professional conduct.

The survey was anonymous and the reporting of incidents voluntary. The CED only considered the complete replies on-line. One reply was received on paper and entered online by CED staff.

III – Survey results - general findings

1. **Number of incidents reported:** 30
2. **Countries:** 7 (Norway, Ireland, Greece, Lithuania, Estonia, Portugal, Bulgaria)
3. **Undesirable effect:**



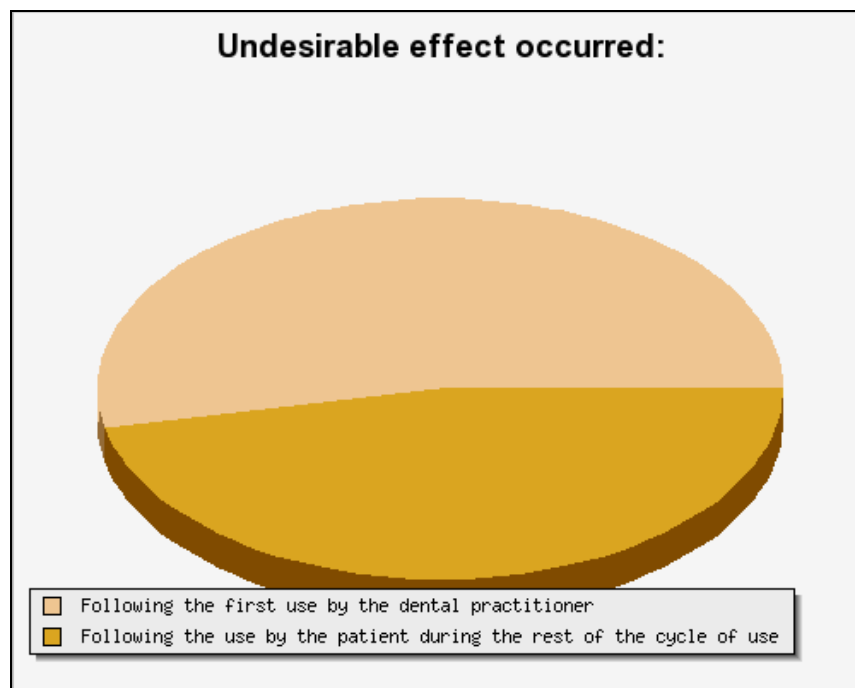
26 replies reported that the undesirable effect was sensitivity, of which 9 also reported soft tissues inflammation/ ulceration, of which 5 also reported pain.

3 replies reported *other* undesirable effects, where a first was interdental papillar necrosis, the second was that teeth developed a blotchy appearance and became very unsightly, and the third did not provide an explanation.

1 reply reported that the undesirable effect was allergy.

Conclusion: the main undesirable effect is sensitivity with very few allergic reactions. These are usual side effects and correspond to scientific literature.

4. **Undesirable effect occurred:**

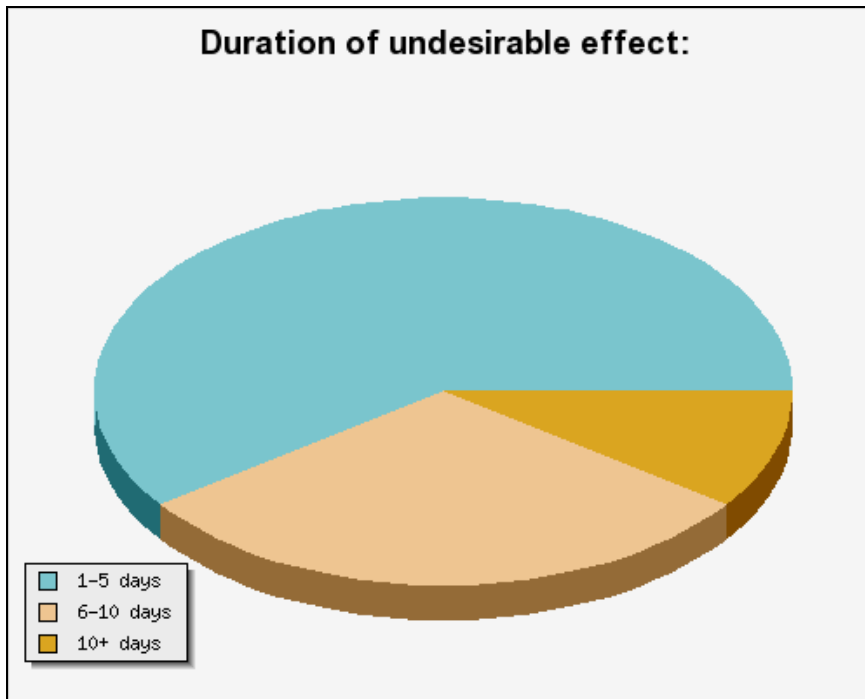


16 replies reported that the undesirable effect occurred following the first use by the dental practitioner.

14 replies reported that the undesirable effect occurred following the use by the patient during the rest of the cycle of use.

Conclusion: treatment in office or at home have no influence on undesirable effects.

5. Duration of undesirable effect:



18 replies reported that the undesirable effect lasted 1-5 days.

9 replies reported that the undesirable effect lasted 6-10 days.

3 replies reported that the undesirable effect lasted more than 10 days.

Conclusion: undesirable effects are transient, lasting on average just a few days.

6. Material used

14 replies reported concentrations between 3.7-6% of hydrogen peroxide (11-16.62% carbamide peroxide).

12 replies reported concentrations between 0.1-3.6% of hydrogen peroxide (0.3-10% carbamide peroxide).

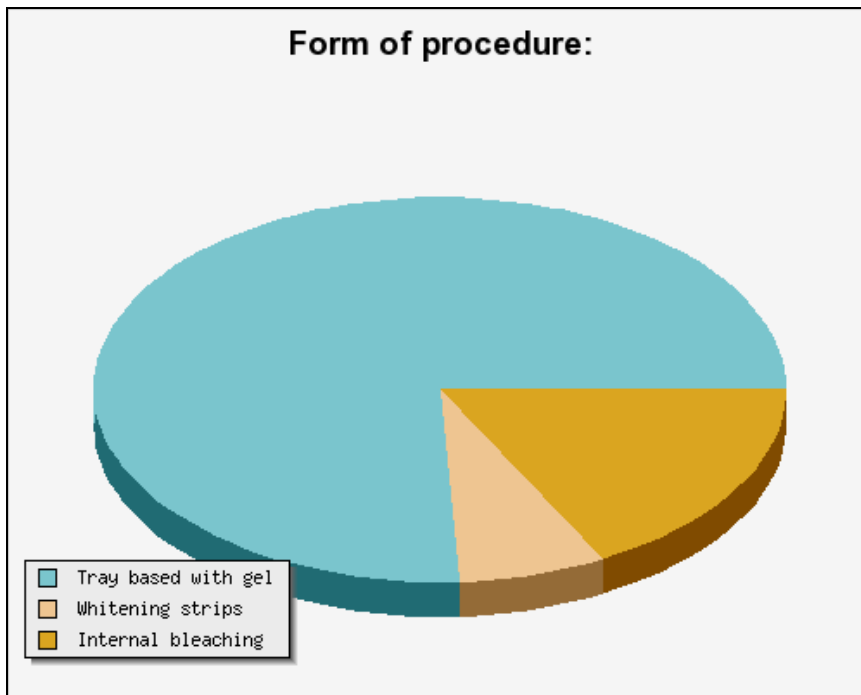
1 reply reported concentration of 15% of hydrogen peroxide.

1 reply reported concentrations of 37,5% of hydrogen peroxide.

2 replies did not specify the substance used, although the concentrations mentioned were 37% and 46% respectively.

Conclusions: the regulation is not always enforced, products over 6% of hydrogen peroxide (H₂O₂) are available on the market. Four out of thirty responses indicated that tooth whitening products above 6% of H₂O₂, that is to say above the limit from Annex III, entry 12 (e) of the Regulation No 1223/2009 (the Cosmetics Regulation), had been used. These four replies reported that the undesirable effect was sensitivity, of which one also reported soft tissues inflammation/ ulceration. They further reported that the undesirable effect lasted 1-5 days.

7. Form of procedure:



22 replies reported that the form of procedure was tray based with gel, of which 1 was also internal bleaching.

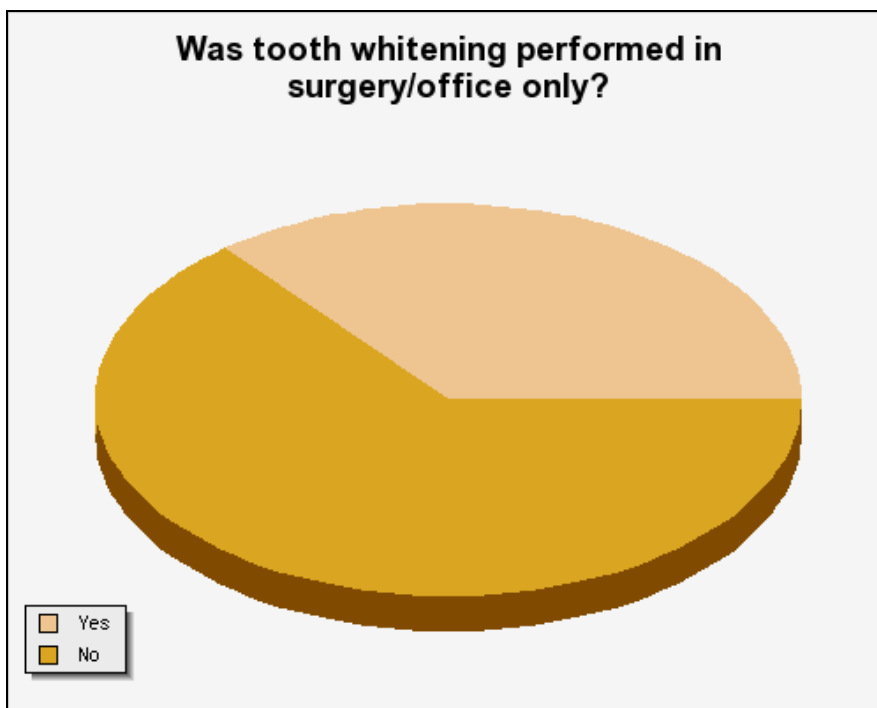
3 replies reported that the form of procedure was internal bleaching only.

2 replies reported that the form of procedure was whitening strips, of which 1 was also internal bleaching.

2 replies reported that the form of procedure was *other*, where one was with zoom lamp and the second was laser bleaching.

Conclusion: the majority of treatments which caused undesirable effects were performed with trays (however, this is also the most common form of procedure).

8. Was tooth whitening performed in surgery/office only?



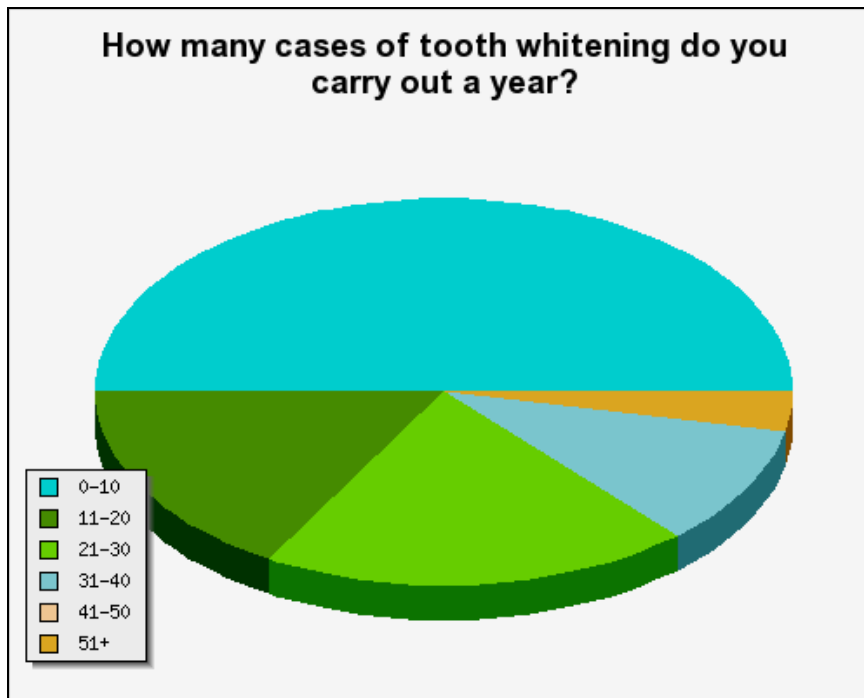
16 replies reported that tooth whitening **was not** performed in surgery/office only.

9 replies reported that tooth whitening was performed in surgery/office only.

5 respondents skipped this question.

Conclusion: the majority of treatments are initiated in surgery and continued under the supervision of the dentist at home for the rest of the cycle of use.

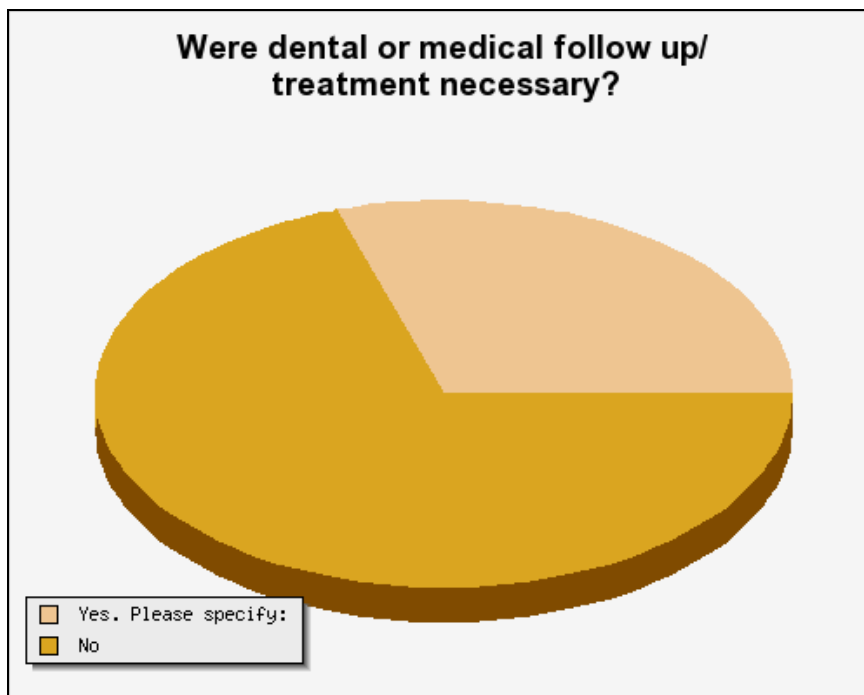
9. How many cases of tooth whitening do you carry out a year?



15 replies reported between 0-10 cases a year
5 replies reported between 11-20 cases a year
6 replies reported between 21-30 cases a year
3 replies reported between 31-40 cases a year
0 replies reported between 41-50 cases a year
1 reply reported more than 50 cases a year

Conclusion: The collection of data about the actual number of tooth whitening procedures carried out per year is very difficult. Nevertheless, the fact that only one person reported more than 50 procedures a year suggests that it is not a very common procedure, compared to other standard dentistry procedures.

10. Were dental or medical follow up / treatment necessary?



21 negative replies
9 positive replies, of which only three provided further specifications. One reply specified that treatment was now in progress using tooth mousse to rehydrate and restore original colour; a second reply specified "in office" and a third reply specified "for sensitivity".

Conclusion: the majority of undesirable effects do not require follow-up treatment.

11. Any observations? No additional observations were received.

IV – Conclusions

These conclusions are a summary of what has been reported by individual dentists:

- **the potential risks associated to the survey identified in the conclusions of the first report are still valid (please see chart below).**

Risk	Preventive action	Potential action
Lack of response to the survey	Send reminders to CED members every two months; raise awareness for the survey at internal events; create a page in the CED website to disseminate the information; use online survey tools, CED members requested to translate the questionnaire in their national language/s.	Continue to disseminate as before; CED members should continue to dialogue with other national relevant stakeholders; (e.g ministries, patients' organisations, dental schools); raise awareness using social media (e.g. twitter); make translations available in CED dedicated webpage.
False reporting by non-dentists	Survey's link only provided to CED Members, members' membership and members' non-members.	

- **the regulation is not always enforced, products over 6% of hydrogen peroxide are available on the market.**
- **in the vast majority of cases, the use of tooth whitening is safe. The most common undesirable effect is sensitivity, followed by gingival irritation. Both side effects are transient.**
- **the findings are in line with the general scientific literature on undesirable effects caused by tooth whitening products.⁴**

⁴ The CED believes that it is important to put in perspective the few undesirable effects reported in the survey by quoting scientific literature on the side effects of tooth whitening in general. The literature shows that:

- side effects of sensitivity are transient; once the whitening treatment is completed sensitivity stops; the main sensitivity is at day three, when there is maximum saturation of oxygen inside the tooth;
- allergy is extremely rare;
- gingival ulceration is not common and the area heal; and
- blotchy teeth is not common and is due to the anatomy and internal structure of the tooth. The tooth whitening process will even out the blotchy appearance. The effect is transient.

Literature:

- Home-based chemically-induced whitening of teeth in adults, Hasson H, et al. Cochrane Database Syst Rev, <http://www.ncbi.nlm.nih.gov/m/pubmed/17054282/?i=5&from=/25998351/related>
- Assessment of efficacy and post-bleaching sensitivity of home bleaching using 10% carbamide peroxide in extended and non-extended bleaching trays, Morgan S, et al. Br Dent J. 2015, <http://www.nature.com/bdj/journal/v218/n10/full/sj.bdj.2015.391.html>;
- Clinical performance of topical sodium fluoride when supplementing carbamide peroxide at-home bleaching gel, Barcellos DC, et al. Gen Dent. 2015 May-Jun, <http://www.ncbi.nlm.nih.gov/m/pubmed/25945764/?i=2&from=sensitivity%20tooth%20whitening>.

ANNEX I

SECOND CED SURVEY: DENTIST REPORT ON UNDESIRABLE EFFECTS/ ADVERSE REACTIONS 2013-2014

Welcome to the Second CED survey!

Please complete this questionnaire in relation to problems that have occurred in any tooth whitening case, reported by the patient himself or observed by you, for each patient. Tick in the appropriate box or write your comments when asked.

This information is being collected to support the ongoing availability of tooth whitening through dentists. **This questionnaire is anonymous. Only summary results will be shared with the European Commission through a report on an annual basis. The report shall be made public.**

Please note that under [paragraph 4 of Article 23 of the Cosmetics Regulation 1223/2009](#), when end users or health professionals report serious undesirable effects to the competent authority of the Member State where the effect occurred, that competent authority shall immediately transmit the information on the cosmetic product concerned to the competent authorities of the other Member States and to the responsible person.

Thank you for your time!

- 1) Country:
- 2) Date of the report:
- 3) Undesirable effect:
- Sensitivity
 - Soft tissue inflammation/ulceration
 - Allergy
 - Pain
 - Other:
- 4) Undesirable effect occurred:
- Following the first use by the dental practitioner
 - Following the use by the patient during the rest of the cycle of use
- 5) Duration of undesirable effect:
- 1-5 days
 - 6-10 days
 - 10+ days
- 6) Material used:
- 0.1-3.6% hydrogen peroxide (0.3-10% carbamide peroxide)
 - 3.7-6.0% hydrogen Peroxide (11-16.62% carbamide peroxide)
 - Other:
- 7) Form of procedure:
- Tray based with gel
 - Whitening strips
 - Internal bleaching
 - Other
- 8) Was tooth whitening performed in surgery/office only?
- Yes
 - No
- 9) How many cases of tooth whitening do you carry out a year?
- 0-10
 - 11-20
 - 21-30
 - 31-40
 - 41-50
 - 51+
- 10) Were dental or medical follow up/ treatment necessary?
- Yes. Please specify:
 - No
- 11) Any other observations, please specify: