Long term follow up of Noma patients after surgical, nutritional and mental health interventions at the Noma Children's Hospital in northwest Nigeria, 2018

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Version 3, 13th June 2018

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Data collection and analysis by	MSF OCA
Collaborating institutions	Usman Danfodiyo University Teaching Hospital (UDUTH)

Summary

Background

Noma is a little understood, rapidly progressing gangrenous infection of the oral cavity, associated with a reported 90% mortality rate . Noma mostly affects children under the age of five, and those who survive have severe facial disfigurements (2) and multiple physical impairments such as difficulty eating, seeing and breathing. Noma can also cause stigmatization due to these impairments . The incidence of Noma is estimated to be 6.4 per 1000 children , and the World Health Organisation estimate that 140 000 children contract Noma each year . Noma is thought to be most prevalent along the Noma belt which stretches from Senegal to Ethiopia , however Noma cases have recently been reported in the United Kingdom, United States , Afghanistan , South Korea and Laos . Little is known about Noma as the majority of cases live in underserved areas, difficult to reach locations, the mortality rate is high and the disease often goes undiagnosed.

Noma starts as an inflammation of the gums, similar to a mouth ulcer, which then leads to the rapid destruction (one week) of the jaw, lip, cheek, nose and sometimes eye . During the first active stages of the disease, antibiotic treatment and wound dressing are effective forms of care, once Noma becomes inactive, patients can survive into adulthood but require extensive reconstructive surgery. The pathogenic cause of Noma is unknown . Noma typifies the complex interactions between extreme poverty, severe malnutrition, poor oral hygiene practices, limited access to high quality health care and co-morbidities with infections such as measles , malignancies, particularly leukaemia , Human Immunodeficiency Virus (HIV) and Crohn's Disease .

Long term outcomes of Noma treatment are difficult to ascertain due to inconsistent follow up because of the remote locations of home villages of patients and difficulties with access to health care assessments. A 2010 paper on the outcome of trismus release in Noma patients in northwest Nigeria (patients from the Noma Children's Hospital), showed that the long term results of trismus release were poor with only 39% of patients showing improvement in mouth opening . This shows a need to carefully monitor outcomes to try to ascertain what factors favour positive outcomes so that these can be the focus of treatment plans.

Médecins Sans Frontières (MSF) runs programs at the Noma Children's Hospital (NCH) in Sokoto, northern Nigeria, and currently assists with surgical interventions for the patients who have survived and sought care at the hospital. Community outreach, active case finding, follow up assessments and prevention programming are also supported by MSF. These projects place MSF in a unique position to study Noma, and to add to the scant body of knowledge around the disease.

In 2017, MSF conducted a comprehensive descriptive study of the Noma patients treated since 2015 in the project in addition to a case control study for Noma patients. Results from these studies indicated that current routine data collection was sub-optimal. In order to be able to track clinical outcomes of Noma patients, more robust data collection and longer term follow up is needed.

The current study aims to address one of the highlighted gaps from the 2017 case review which is the absence of comprehensive information on surgeries performed (including techniques) and clinical outcomes of Noma patients after surgery (in terms of surgical,

anaesthesia-related and post-surgical complications, including infections) and outcome information after discharge from the hospital. Additionally, it will aim to establish better ways in which to ensure that current medical data on previous medical and vaccination history of each individual Noma patient are being accurately collected and analysed. Only by implementing a systematic and controlled method of data collection in conjunction with systematic follow up will our medical teams learn from current interventions and be able to use these recommendations for improved clinical management.

Aims and objectives

Aim

To assess previously cared for patients, and to set up a robust prospective surgical outcome assessment program incorporating assessments at admission, pre-operatively, discharge, 6 and 12 months after the date of their last surgery.

Objectives

- To update the Noma database to ensure all new variables added in the latter section of the project can be inputted
- To ensure all information in the paper medical record charts is uploaded onto the database through a retrospective chart review
- To assess patients cared for at the Noma Children's Hospital since 2015, focussing on trismus, maximum mouth opening and survival rates after treatment. Assessments will be conducted on those who live in Sokoto and Kebbi states.
- To estimate factors associated with survival (including morbidities other than Noma) of Noma patients (including assessing the effect of vaccination status, previous clinical history and illness, Noma status upon admission, treatment received);
- To prospectively assess all patients at admission, pre-surgery, discharge from last surgery, 6 and 18 months after their last date of surgery focussing on aspects of the Noma classifications system (Nose, Outer Lining, Inner Lining, Trismus, Upper Lip, Lower lip, Peculiarities- NOITULP), maximum mouth opening and survival rates after treatment.
- To prospectively document and describe surgical outcomes as well as post intervention complication rates (surgical, anaesthesia and post-operative infection) in all Noma patients
- To estimate risk factors associated with negative outcomes (i.e. surgical, anaesthesia complications or post-operative infections);

We aim to use the information generated by these objectives to improve the quality of care of Noma patients in northwest Nigeria and contribute to best practices guidance for medical care of this condition.

Methods

This study will be made up of five main sections:

1- *Update existing database* to include information gathered at later stages of the project
2- *Chart review* to fill in any gaps in the database with a special focus on including surgeries performed, techniques used, surgical complications, anaesthesia complications and post-operative infection.

3- *Retrospective assessment* for patients cared for at the hospital since 2015, with a focus on trismus, maximum mouth opening and survival rates after treatment.
4- *Factors that favour survival*- Based on the information found in the previous sections, an assessment of factors that survival, using logistic regression models will be conducted. Things such as vaccination status, previous clinical history and illness, Noma status upon admission, treatment received and nutritional status will be assessed.
5- *Prospective surgical outcome assessment* using standardised tool, conducted at admission, pre-operatively, at discharge from hospital after last surgery, 6 and 12 months after the date of their last surgery. Assessment will include survival rates, physical development, psychosocial development, speech and communication, and assessing deviations from expected post-operative course.

Outcomes

Expected outcomes for the project are as follows:

- An estimation of the post discharge survival rate of Noma patients
- As estimation of factors associated with survival of Noma patients which will allow for these factors to be focussed on during care provision so as to optimise survival rates and positive outcomes
- An estimation of outcomes of previously cared for Noma patients
- The creation of a surgical outcome measurement system which will enable ongoing assessment of outcomes of interventions. This system will facilitate a better understanding of the outcomes of the program and allow for monitoring and evaluation of the program to assess effectiveness. The program will also offer potential insights into changes that could be made for ongoing improvement of care provision.
- Strengthening of routine data collection by conducting refresher training and clear briefings of all medical teams. Particularly, the data collection around previous medical history, vaccination history, surgical interventions, surgical/anaesthesia and post-surgical complications and status of patient at discharge will be improved. Training on ethical data collection practices and privacy protection will also be held.

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Abbreviations

HIV	Human Immunodeficiency Virus
MSF	Médecins Sans Frontières
NCH	Noma Children's Hospital
TB	Tuberculosis
TH	Traditional Healer
UDUTH	Usman Danfodiyo University Teaching Hospital
WHO	World Health Organization

Background

Noma, also known as cancrum oris, is a little understood, rapidly progressing infection of the oral cavity, associated with a reported 90% mortality rate . Noma mostly affects children under the age of five, and those who survive have severe facial disfigurements and multiple physical impairments such as difficulty eating, seeing and breathing. Noma can also cause stigmatization due to these impairments . The incidence of Noma is estimated to be 6.4 per 1000 children , and the World Health Organisation estimate that 140 000 children contract Noma each year . Noma is thought to be most prevalent along the Noma belt which stretches from Senegal to Ethiopia , however Noma cases have recently been reported in the United Kingdom, United States , Afghanistan , South Korea and Laos . Little is known about Noma as the majority of cases live in underserved areas, difficult to reach locations, the mortality rate is high and the disease often goes undiagnosed.

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Long term outcomes of Noma treatment are difficult to ascertain due to inconsistent follow up because of the remote locations of home villages of patients and difficulties with access to health care assessments. A 2010 paper on the outcome of trismus release in Noma patients in northwest Nigeria (patients from the Noma Children's Hospital), showed that the long term results of trismus release were poor with only 39% of patients showing improvement in mouth opening . This shows a need to carefully monitor outcomes to try to ascertain what factors favour positive outcomes so that these can be the focus of treatment plans.

Médecins Sans Frontières (MSF) runs programs at the Noma Children's Hospital (NCH) in Sokoto, northern Nigeria, and currently assists with surgical interventions for the patients who have survived and sought care at the hospital. Community outreach, active case finding, follow up assessments and prevention programming are also supported by MSF. These projects place MSF in a unique position to study Noma, and to add to the scant body of knowledge around the disease.

In 2017, MSF conducted a comprehensive descriptive study of the Noma patients treated since 2015 in the project in addition to a case control study for Noma patients. Results from these studies indicated that current routine data collection was sub-optimal. In order to be able to track clinical outcomes of Noma patients, more robust data collection and follow up is needed. Outcomes are important to monitor for several reasons, not the least being the increased risk of mortality, one study showed that the occurrence of a post-operative complication within the 30 days after surgery, reduced median patient survival by 69% . There is consensus that quality assessment of outcomes is important however the definition of outcomes vary between individual clinicians or institutions and there are limited set

standards for grading postoperative outcomes , and no known Noma outcome assessment tools.

The current study aims to address one of the highlighted gaps from the 2017 MSF report, which is the absence of comprehensive information on details of surgeries performed, clinical outcomes of Noma patients after surgery (in terms of surgical, anaesthesia-related and post-surgical complications, including infections) and outcome information after discharge from the hospital. Additionally, it will aim to establish better ways in which to ensure that current medical data on previous medical and vaccination history of each individual Noma patient are being accurately collected and analysed. Only by implementing a systematic and controlled method of data collection in conjunction with systematic follow up will our medical teams learn from current interventions and be able to use these recommendations for improved clinical management.

Research question

What are the long term outcomes of Noma patients treated at the Noma Children's Hospital in Sokoto, Nigeria?

Study aim and objectives

Aim

To assess previously cared for patients, and to set up a robust prospective surgical outcome assessment program incorporating assessments at admission, pre-operatively, at discharge, 6 and 12 months after the date of their last surgery.

Objectives

- To update the Noma database to ensure all new variables added in the latter section of the project can be inputted
- To ensure all information in the paper medical record charts is uploaded onto the database through a retrospective chart review
- To assess patients cared for at the Noma Children's Hospital since 2015, focussing on trismus, maximum mouth opening and survival rates after treatment. Assessments will be conducted on those who live in Sokoto and Kebbi states.
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- To prospectively document and describe surgical outcomes as well as post intervention complication rates (surgical, anaesthesia and post-operative infection) in all Noma patients
- To estimate risk factors associated with negative outcomes (i.e. surgical, anaesthesia complications or post-operative infections);

We aim to use the information generated by these objectives to improve the quality of care of Noma patients in northwest Nigeria and contribute to best practices guidance for medical care of this condition.

Methodology

Study Design

This study will be made up of five main sections (Figure 1):

1) **Noma database update**: the current database will need to be adapted in order to capture additional information gathered during the latter parts of the project including the post-operative assessment tool which will be conducted at admission, pre-operatively, at discharge, 6 and 12 months after the date of their last surgery.

2) **Chart review**: conducted of all exiting charts for patients admitted to the Noma Children's Hospital since MSF began partnering with the Ministry of Health to provide care (2015). This review will aim to complete missing data in the current database to ensure all information in the database is up to date and as complete as possible, including the types of surgeries that have been performed and which techniques were used for these surgeries, and all post intervention complication rates (surgical, anaesthesia and post-operative infection).

3) **Retrospective patient assessments**: this will target all patients cared for since 2015 (when MSF became involved with the program) who live in Sokoto or Kebbi states. Deaths and all outcomes will be added to the newly updated database. Data retrieved from the hospital database includes age distribution, sex, area of residence, time of onset, previous clinical history, grading of Noma at start of program, operations sustained during program admission, techniques used during surgeries, as well as complications sustained (surgical, anaesthesia and post-operative infection).

Data collected from traced patients during the retrospective assessment includes-

- Mouth opening measurement
- Weight
- Height
- Age
- MUAC measurement
- Verbal autopsy (if applicable)

4) **Factors that favour survival**: to estimate the factors associated with survival for Noma patients. This will be conducted by reviewing information in the now up to date database, and running logistic regression models to assess the factors which favour survival. Things such as vaccination status, previous clinical history and illness, Noma status upon admission, treatment received and nutritional status will be assessed.

5) **Prospective Surgical Outcome Assessments**: to establish up a systematic, continual monitoring system that will assess outcomes of care. Patients will be

assessed using a standardised tool at admission, pre-surgery, discharge after last surgery and at 6 and 12 months post-date of last surgery.

As part of the study we will recruit participants for the study for one year and then follow up with those recruited during that year until the end of their assessments (12 months after date of last surgery). However the assessments will continue as part of the normal programming at the Noma project on a routine basis. This information has been reflected in the protocol. Deaths and all outcomes will be added to the existing database. Pictures will be taken using standardised methods, and these will then be assessed by trained surgeons using the existing, validated Noma grading tool, NOITULP to grade the Noma at different outcome stages. The results from these assessments should continually be looked at by the medical team, and treatment and outreach activities should be adjusted according to results of these assessments.

Data collected from traced patients during the prospective assessment includes-

- Mouth opening measurement
- Weight
- Height
- Age
- MUAC measurement
- Verbal autopsy (if applicable)
- Quality of life questions
- Pictures (for grading of Noma on NOITULP tool)

Figure 1- Study Design

Noma Database Update

- Redesign database to include all new sections needed for latter parts of the project
- Adjust databse configertion to include the outcome assessments which will be conducted

Chart Review

- Chart review of all patients cared for since 2015
- Types of surgeries as well as surgical techniques noted
- All complications noted in database
- Other gaps in existing database filled where possible
- Assessment of surgical, anaesthesia complications, post-operative infections

Retrospective Patient Assessments

- Follow up with all patients since 2015 who live in Sokoto or Kebbi states
- Conduct a descriptive assessment of outcomes for Noma patients

Factors that Favour Survival

- Update database with all findings during assessments in the section above
- Conduct analysis on what factors favour survival
- Incorporate findings into care provided at the NCH, and share findings

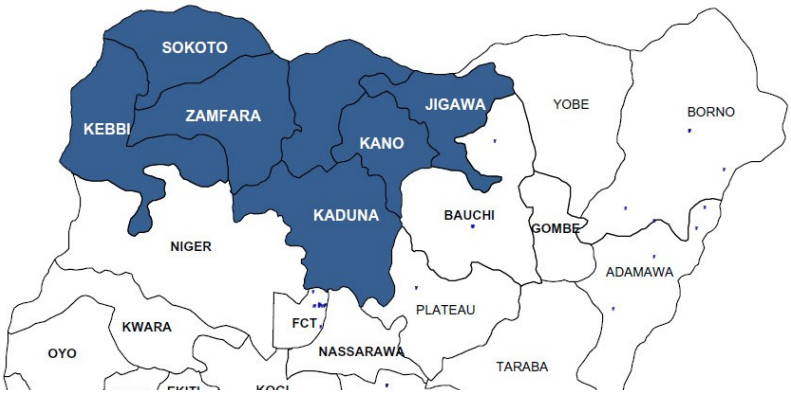
Prospective Surgical Outcome Assessments

- Create standardised outcome assessment form
- Use standardised form to assess outcome at admission, pre-surgery, discharge, 6 and 18 months post op
- Continual monitoring of database to ensure all complications are noted and all details are correct
- Continuing assessment on factors that favour survival and positive outcomes to inform adaptive care provision

Setting

The Noma Children's Hospital in Sokoto has been providing treatment for Noma patients for many years, and, since 2015, MSF has supported Noma initiatives at the hospital. All sections of this study will be conducted at the Noma Children's Hospital in Sokoto, and in Sokoto and Kebbi States (Figure 2 below).

Figure 2 Map of northern Nigeria



Noma Database Update

Data collection

The update of the Noma database will focus on ensuring the database needs of the following sections of the project are catered for. Specific sections of the database will need to be adjusted and added to in order to accommodate the new information that will be gathered.

Specific Outputs

The main output from this section is an up to date, ready to use high functioning database that will enable all future sections to be completed.

Chart Review

Study Population

The retrospective chart review will be conducted on records for all MSF supported patients admitted to the Noma Children's Hospital since 2015 which is when MSF first began partnering with the institution.

Sampling and recruitment

No specific sampling or recruitment strategies will be put in place for this section of the project as the data utilised will be routinely collected data gathered retrospectively from charts that are in the hospital.

Data collection

The data for the retrospective review will be conducted by retrieving patient files from the filing room at the Noma Children's Hospital. These will then be reviewed and any missing data in the existing database will be updated, and any additional information such as kinds of

surgeries and techniques used as well as post-operative complications will be included in the database. The data collection will be done in collaboration with one of the expat surgeons who forms part of the surgical intervention team, this surgeon could remain in country post intervention to conduct the retrospective review in conjunction with the PI and research team.

Inclusion and exclusion criteria

Records for all MSF supported patients admitted to the Noma Children's Hospital since 2015 will be included.

Data Analysis

Once the database has been updated with all data from the medical record charts, the data will be analysed in terms of epidemiological and clinical information to determine frequencies and proportions of different variables: age distribution, sex, area of residence, time of onset, previous clinical history, grading of Noma at start of program, operations sustained during program admission, techniques used during surgeries, as well as complications sustained (surgical, anaesthesia and post-operative infection). Analyses will be performed using Stata 14.

Specific Outputs

Training will be held with all medical teams, this training will focus on improving the data quality and the data collection practices around previous medical history, vaccination history, surgical interventions, surgical/anaesthesia and post-surgical complications and status of patient at discharge. Training on ethical data collection practices and privacy protection will also be held. This training will attempt to improve data quality in the project.

A descriptive report on the post-operative complications as well as an assessment of the surgical procedures and techniques used which will assist the team in gaining an understanding of the surgeries performed and techniques used during these surgeries as well as the complication rates (surgical, anaesthesia and post-operative infection) for all Noma patients operated on since 2015.

Retrospective Patient Assessments

These assessments will focus on assessing presence of trismus, maximum mouth opening and survival rates in patients who have completed their final round of surgery, 6 to 12 months after the date of their last surgery.

Study Population

The retrospective assessments will be conducted on patients who have been cared for at the Noma Children's Hospital since 2015 who are located in Kebbi and Sokoto states, who have had their last surgery. These states were chosen for this study due to access and security issues. The first round of follow ups will focus on those whose last operation date was 6 months prior to data collection, the second round on those operated on 12 months prior to data collection.

Sample Size

Based on patient reported in the existing database, we estimate that 200 patients will have been cared for since 2015, and 80% of these would come from either Sokoto or Kebbi states, and so 160 patients would be eligible to be included in the assessment. Due to previous

experience running projects in the area, we expect 33% of these will not be able to participate in the assessments, we expect some patients will not wish to participate, and we expect to not be able to reach a certain number of patients due to poor road access. Thus we estimate 106 patients will be available for the assessment part of the study; however we will attempt to reach all patients. We will conduct assessments using a tiered system, beginning with those most recently operated on and then moving to those operated on 12 months prior to data collection, this is expanded upon in the recruitment section below.

We will attempt to follow up with all previously cared for patients; and this will enable a description of outcomes within this group. We cannot at this stage say whether or not we will have enough power to detect certain events at this stage as we have no previous data to base our power calculations on and we are not yet sure which outcomes we will measure.

Inclusion and exclusion criteria

Inclusion: All patients cared for at the Noma Children's Hospital since 2015 and living in Sokoto and Kebbi will be included.

Exclusion: All those patients scheduled for follow up surgery will not be included. However it should be noted that they are followed as part of routine clinical management.

Sampling and recruitment

All patients cared for at the hospital since 2015 will be followed up with in their home villages, or at the Noma Children's Hospital. There will be a tiered follow up system starting with those who were operated on 6 months prior to data collection, followed by those operated on 7 – 12 months prior to data collection. Once these main priority groups have been followed up with, the remaining patients will be assessed. The routinely collected data in the database includes home addresses and telephone numbers for patients, this will enable contact to be made with patients who will be asked if they would be willing to be assessed as a part of the study. If they consent to being part of the study, the research team will visit them in their home village, or if the patient prefers, they can come to the Noma Children's Hospital for assessment.

Data collection

Data collection will be completed using paper forms which will then be uploaded to the database. A standardised retrospective measurement tool (Appendix 1), customised to the setting and specific assessment will be designed in conjunction with the medical team at the hospital, a surgical advisor and the program team at the hospital. This tool will focus on the presence of trismus, maximum mouth opening and survival rates after treatment. Due to the retrospective nature of this section, baseline data will be made up of the routinely collected data and as such comparison will be limited.

Deaths from causes other than Noma or deaths from unknown causes will also be recorded. The survival rate assessed will include these deaths from things other than Noma. If the cause of death is known or recorded in medical charts, this will be noted down. If the death occurred at home, a verbal autopsy form will be completed with the family (Appendix 2 and Appendix 11 for Informed Consent for Verbal Autopsy).

Trismus is defined as any restriction in mouth opening, including restriction caused by infection, trauma, surgery, or radiation . Trismus is an important indicator to monitor as it can lead to complications such as poor oral hygiene, reduced access for oral examination and dental procedures, aspiration and related complications, malnutrition, speech deficits, airway

compromise and pain . Maximum mouth opening will be measured during the assessments, and the measurement can then be applied to an existing scale:
0 = normal mouth opening: > 40 mm
1 = mouth opening 20 mm up to 40 mm
2 = mouth opening > 0 mm up to 20 mm
3 = no mouth opening = ankylosis

Once this scale has been applied at multiple time points, a comparison can be made to assess if the mouth opening has increased or not.

For all patients followed up with, regardless of participation in the study, if any complication has arisen, or any treatment is needed, the patient will be referred directly to the correct health care institution for timely treatment.

Data Analysis

Once the database has been updated with all information gathered during the assessments, the data will be analysed to determine frequencies and proportions of the survival rate of previously cared for Noma patients. Analyses will be performed using Stata 14.

Specific Outputs

A descriptive report will be put together describing the post discharge survival rate of Noma patients for those patients who were followed up with.

Factors that Favour Survival

This analysis will be conducted to estimate factors associated with survival of Noma patients. Factors assessed will include vaccination status, previous clinical history and illness, Noma status upon admission and treatment received.

Study Population

The assessment on factors that favour survival will be conducted on records for all MSF supported patients admitted to the Noma Children's Hospital since 2015 which is when MSF first began partnering with the institution. The database will be updated with all variables from the chart review, as well as all information noted during the retrospective assessment section of the project.

Sampling and recruitment

The analysis on factors that favour survival will be conducted on records for all MSF supported patients admitted to the Noma Children's Hospital since 2015 who have been followed up with successfully during the assessment section of the project, and as such, have a known information on trismus, maximum mouth opening and survival. No specific sampling or recruitment strategies will be put in place for this section of the project as the data utilised will be that collected in the previous sections of the project.

Data collection

The data for this section will be taken from the up to date database, which has all information from the previous sections recorded.

Inclusion and exclusion criteria

Records for all MSF supported patients admitted to the Noma Children's Hospital since 2015 who have known information on trismus, maximum mouth opening and survival will be included.

Data Analysis

Factors that favour survival will be examined using logistic regression. Single and multivariate analysis will be conducted. Frequencies of exposure to each of the common risk factors will be calculated. The odds of exposure to those individual risk factors will be calculated in those with trismus or those who have died and those without trismus and who are still alive separately and concurrent odds ratios (ORs) for these with their respective 95% confidence intervals (95%CI) will be calculated. Depending on the outcomes of the unadjusted analysis we will select those exposures that appear to have an association with the presence of trismus and death from the unadjusted analysis as well as other variables which we might consider to be confounders in the associations demonstrated in the unadjusted analysis (i.e. age) and include them in a multivariable logistic regression model. Risk factors with a p-value of less than 0.2 in the unadjusted analysis will be included in the adjusted analysis if the above examination makes this option seem viable and accurate for the model. Variables will be removed from the multivariate model using manual backwards stepwise elimination using likelihood ratio tests. The results of this model will include adjusted ORs and respective 95% CI. The impact of effect modification will also be explored for certain factors. Results will be classified to look at possible intervention/prevention opportunities. All analysis will be conducted using Stata 14 and Excel.

Specific Outputs

A report detailing an estimation of factors associated with survival of Noma patients will be put together which will allow for these factors to be focussed on during care provision so as to optimise survival rates.

Prospective Surgical Outcome Assessments

Standardised assessments will be conducted which assess the outcomes of all patients after care at Noma Children's Hospital. In order to assess these outcomes, a standardised data tool will be used to conduct assessments of patients at admission, pre-operatively (one or two days before each surgery), at discharge from hospital after final surgery, 6 and 12 months after the date of their last surgery. Comparisons will then be made by assessing the post-operative results to the admission and pre-surgery results. These comparisons will be able to give information on whether the surgical outcome is expected (goof outcome) or it deviates from expected outcome (bad outcome).

Study population

The prospective outcome assessments will be conducted on all patients being admitted at the Noma Children's Hospital, and at various other time points during their care in the program.

Inclusion and exclusion criteria

Inclusion: Inclusion is voluntary and inclusion criteria for the outcome assessment are:

(i) Noma patients admitted at the Noma Children's Hospital for the first time;

(ii) Aged 18 years or more or have a caretaker aged 18 years or more who can consent to patients participation,
(iii) Willing to participate in the assessment.

Exclusion:

(i) Those unwilling to participate and or unwilling to provide consent
(ii) Non-NOMA patients, even though MSF supported

Sampling and recruitment

Going forward, all patients being cared for at the Noma Children's Hospital who provide consent will be assessed prospectively at admission, pre-operatively (one or two days before all surgeries), at discharge from hospital after final stage of surgery and at 6 and 12 months after the date of their last surgery in their home villages, or at the Noma Children's Hospital to assess outcomes of surgery. The in hospital assessments will be conducted by the medical team and the post discharge assessments will be conducted by the outreach team.

Data collection Participants will be assessed using a standardised data collection tool at admission, pre-operatively (one or two days before each surgery), at discharge from hospital after final surgery, 6 and 12 months after the date of their last surgery.

As part of the prospective component of the study we will recruit participants for the study for one year and then follow up with those recruited during that year until the end of their assessments (12 months after date of last surgery). Based on previous admissions to the hospital, we estimate that during the 12 months we will include between 75 and 100 patients in the study. We must stress that even though we intend to look at the data in a study environment, the system established for the prospective study will be integrated into our routine clinical care and follow up of Noma patients. Thus even after the 12 month period for the study inclusion, follow ups will continue with all patients after this time.

Data collection will be completed using paper forms which will then be uploaded to the database. A standardised outcome measurement tool, customised to the setting and specific treatment offered at the Noma Children's Hospital will be designed in conjunction with the medical team at the hospital, a surgical advisor and the program team at the hospital and will be in line with other existing outcome measurement tools . Loss of function and trismus will be measured in percentage and millimetres respectively and then applied to existing NOITULP Noma grading tool (Appendix 3). This customised Noma surgical outcome measurement tool will gather information including mortality, deviations from expected post-operative outcomes, physical and self-reported psychosocial development (detailed in Table 2).

Deaths from causes other than Noma or deaths from unknown causes will also be recorded. The survival rate assessed will include these deaths from things other than Noma. If the cause of death is known or recorded in medical charts, this will be noted down. If the death occurred at home, a verbal autopsy form will be completed with the family (Appendix 2 and Appendix 11 for Informed Consent for Verbal Autopsy).

Trismus is defined as any restriction in mouth opening, including restriction caused by infection, trauma, surgery, or radiation . Maximum mouth opening will be measured during the assessments, and the measurement can then be applied to an existing scale:
0 = normal mouth opening: > 40 mm
1 = mouth opening 20 mm up to 40 mm
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3 = no mouth opening = ankylosis

Once this scale has been applied at multiple time points, a comparison can be made to assess if the mouth opening has increased or not.

Table 1- Outcome Measurement Tool Categories

Outcome Category	*Included Outcomes*	*Instruments Used*	*Data Source*
Mortality	Death	Verbal Autopsy Form	Assessor
Deviation from expected post-operative course	Regrading of Noma through the use of the NOITULP Tool	Loss of function will be measured in percentage and then applied to the NOITULP Tool (Table 2 below)	Three independent surgeons through telemedicine
	Trismus	Maximum mouth opening will be measured in millimetres following the instructions in the SOP for Mouth Opening Measurements (Appendix 4).	Medical Assessor
Physical Development	Change in WHZ, weight for height and height for age	Scale and measuring tape	Assessor
	Eating and drinking	Self-reported scale, or set questions	Patient reported outcome
Psychosocial Development	Social interaction, inclusion	Self-reported	Patient reported outcome

Table 2- NOITULP Scale

NOITULP Scale – Classification for Noma (Nose, Outer Lining, Inner Lining, Trismus, Upper Lip, Lower Lip, Particularities)

	Fractional *Loss* of Anatomical Unit				
	0	**1**	**2**	**3**	**4**
Nose	No loss	1 - 25% lost	26 - 50% lost	51 - 75% lost	76 - 100% lost
Outer Lining	No loss	1 - 25% lost	26 - 50% lost	51 - 75% lost	76 - 100% lost
Inner Lining	No loss	1 - 25% lost	26 - 50% lost	51 - 75% lost	76 - 100% lost
Trismus*	normal mouth opening: > 40 mm	mouth opening 20 - 40 mm	mouth opening 0 - 20mm	no mouth opening= ankylosis	NA

Upper Lip	No loss	1 - 25% lost	26 - 50% lost	51 - 75% lost	76 - 100% lost
Lower Lip	No loss	1 - 25% lost	26 - 50% lost	51 - 75% lost	76 - 100% lost
Particularities **	No particularities	Brief description of particularity:			

* Trismus is not an anatomical unit but a functional problem – the inability to open the mouth properly. It has been included in the system because of its clinical relevance (e.g. for intubation).
**Particularities represent pathologic findings pertinent to reconstruction, i.e.: Loss of lower eyelid tissue (Eyelid retraction by a scarred cheek is not to be noted); Affection of the orbit; loss of an eye is seen quite commonly; Palatal defects; Maxillary sinus defects; Loss of premaxilla; Loss of skin of the chin; Defects of both cheeks.

The outreach team will be trained on the new database, as well as the outcome assessment tools. The outcome assessment plan will be clearly explained to all team members. A monthly report will be generated from the database showing those patients who were operated on 6 and 12 months previously, this report will be given to the outreach team leader who will then integrate the assessments into their monthly activity plan.

The outreach team will take pictures of the patient in accordance with a SOP (Appendix 5), as will the mouth opening measurements (Appendix 4). Once the photographs have been taken, they will be uploaded onto the MSF telemedicine portal and then loss of function will be graded in percentage by three independent surgeons (one from Kaduna and two MSF Noma surgeons), who will be blinded to the other surgeons grading results. The results of loss of function as well as the trismus millimetre opening will then be graded according to the NOITULP scale (Table 2) and included in the Noma database, and can then be assessed by the team on a regular basis, thus making routinely collected data more thorough and this data can then be used to improve care provision.

For all patients followed up with, regardless of participation in the study, if any complication has arisen, or any treatment is needed, the patient will be referred directly to the correct health care institution for timely treatment.

Data Analysis

There will be a continual analysis of the data from the outcome assessments, which will be used to provide an overview of the program. A descriptive analysis will be conducted monthly by the outreach team, assessing the number of patients followed up with, the kinds of outcomes being seen and any other information which the outreach team wants to highlight. This will be passed on to the medical team leader, and if he or the program coordinator deems a more in-depth assessment of the situation, then the Nigerian mission epidemiologist will be contacted.

An annual review of all outcomes of the project should be conducted by the mission epidemiologist to assess factors that favour survival and positive outcomes, and a comparison to previous assessments should be done to assess if there are any new occurrences, or if weight is being added to old assertions. These annual assessments will help guide prevention and care programs and ensure long term follow up outcomes are being assessed which will increase the effectiveness of the program.

Specific Outputs

The main output of this section will be the creation of a robust outcome measurement system which will enable ongoing assessment of outcomes of surgical interventions by program staff. This system will facilitate a better understanding of the outcomes of the program and allow for monitoring and evaluation of the program to assess effectiveness. The system will also offer potential insights into changes that could be made for an ongoing improvement of care provision.

This system will allow for an ongoing assessment of Noma outcomes at various stages post care. A strengthening of routine data collection by conducting trainings with staff around outcome collections and measurement tools will also occur.

Data storage

The Noma database which will house all the information from all sections of this project will only be available in a password protected database at the Sokoto project base to which only certain authorized staff will have access. The paper data collection forms which will be used for outcome assessments will only contain unique identification numbers to identify the patients and when the information on these is entered into the database and quality checking has been conducted, the forms will be kept for 10 years in a locked cupboard at the project site and thereafter destroyed. Although the results of this study may be published, no information that could identify any of the participants will be included. All reports and publications will refer only to anonymous or aggregated data. Nominal data will not be distributed outside the study location or appear in any report or publication.

Confidentiality is paramount, and no information about individual participants or their household members will be accessible to any individuals not directly involved in data entry. Pictures taken for the grading of Noma will be kept in a secure online cloud folder in the existing MSF telemedicine portal, that is password protected, only the PI and surgeons doing the grading will have access to these pictures, they will be deleted from the cameras used to take them immediately after upload and kept in the online storage for 10 years. If publication requires, we may need to show representative pictures, permission for this will be requested at the time of taking the picture and all efforts to anonymise the person in the picture will be taken (e.g. blocking out the eyes where possible).-In some instances it will not be possible to block out the eyes as Noma reconstructive surgeries often involve the whole cheek and/ or the orbit and so it is impossible to show these reconstruction outcomes if blocking out the eyes. Other papers on Noma have followed this same pattern in terms of de-identifying published pictures where possible .

Participant identifiers will not be included in results and disseminated reports. The research team will be required to sign a non-disclosure and privacy form (Appendix 6) stating that they will not discuss information about individuals participating in the study outside of the research team. The research team will ensure the ethical principles of beneficence, non-maleficence, justice, autonomy and respect of persons are adhered to throughout the study.

Quality assurance

During the field work, supervision of field teams will be ensured by the PI. Ten percent of the charts that are entered into the database in the first section of the project will be checked for accuracy and completeness by the PI. Twenty percent of paper retrospective assessment and prospective surgical outcome assessment forms will be checked by the PI on an ongoing basis to ensure they are being entered into the database correctly, this will be done at

random and the PI will compare them to the original paper format to ensure that the data quality is of sufficient quality.

Ethical considerations

The MSF ethical review board, the Usman Danfodiyo University Teaching Hospital (UDUTH) Health Research and Ethics Committee in Nigeria and the Sokoto and Kebbi Ministry of Health Ethics Departments will review the study protocol and it will not be implemented unless approval is obtained from all four boards.

Benefits

For the chart review and factors that favour survival, there will be limited direct benefits to the individual participant. Benefits are mainly limited to the overarching benefit to the population as a whole but the findings of this study may help future Noma patients through improvements to MSF's services. There are two potential direct benefits, firstly, to the at-risk population will come from the strengthening of MSF's current programming by providing essential information from which more effective prevention strategies can be developed. Dissemination of results will help inform other actors, such as the Ministry of Health, MSF Noma Children's Hospital and other organizations involved in Noma care globally by contributing to the body of knowledge around this disease.

Risks

The risks in the study are discussed in the table below, along with the steps that will be taken to mitigate these risks (Table 2).

Table 3- Risks and Mitigation

Risk	Mitigation
Emotional Distress- There is the potential for psychological stress to occur by asking participants to take part in the assessments.	This risk will be mitigated by ensuring well trained staff conducts the assessments and care is taken during assessment tool design to minimize risk, by avoiding distressing questions that are not related to the study objectives. Assessments will be terminated if the assessor observes that the respondent is under undue stress. Regular briefings will be held with assessors throughout the research process to identify issues and provide further training as required. The MSF Psychology team will be available to provide counselling to participants who request or require assistance. This care is available at the NCH and so if necessary, referrals will be made.
Physical Discomfort- there is a chance that the physical examination during the outcome assessment may cause discomfort	This will be mitigated by ensuring well trained staff conduct the assessments, and by ensuring the assessments are minimally invasive in design.
Confidentiality around picture taking	Patients may feel concerned that their pictures may be shared or shown to others; this will be mitigated by ensuring all staff has signed a confidentiality agreement that states they will not share the pictures with anyone outside of the selected few research team members who need access to the photos to complete the grading of

	the Noma cases. The photos will be stored in a secured cloud database on the existing secure MSF telemedicine portal, in a password protected folder which only the PI and surgeons who will be doing the grading will have access to. Participants will each sign an informed consent form regarding the taking of pictures, where confidentiality is assured, and they are given a chance to ask questions about this aspect of the project. They will also be assured that they can decline the request to take photographs, or can stop the process at any time.
Security- The operational area of the Noma project within and outside Sokoto operates at a high level of security; there is a risk of kidnapping for staff working in the project.	In order to mitigate security risks, all assessors will be asked to comply with MSF security guidelines. Prior to departure for any village visits, a Field Trip Request will be completed and sent to the security responsible for the program who must give permission before the trip is authorised. For all authorised trips, assessors will always travel in pairs with a driver. Teams will make contact with the radio room every 30 minutes through the trip. Any breeches in this security plan will lead to standard MSF security procedures being implemented. The security implications for the implementation of the study cannot be planned beforehand and will require adjustments at various stages to ensure all risks are mitigated.
Identifiability	No names will be recorded on the paper assessment sheets; all identifying data will be modified to ensure that the participants cannot be identified.
Confidentiality	A confidentially agreement will be signed by the assessors which will include a guarantee to respect all parties involved in the study; maintain confidentiality and accuracy when assessing patients.
Therapeutic misconception	It will be clearly explained to caretakers that participating in the assessment will not impact upon the care offered at the hospital, it will be explained that by participating they will not be given preferential treatment at the hospital, nor will they have any negative repercussions for the treatment offered. Participation in the study and care provision will remain completely separate.

Reimbursements

No reimbursements will be given for participation in the assessment. As part of the care provided at the hospital, caretakers are reimbursed for transport to and from the hospital, they are also provided with food and shelter while at the hospital. And as such no reimbursement is necessary for the assessment. For many of the assessments, the teams will travel to the patients' location and so no travel reimbursement is necessary. If the patients do come to the hospital for the 6 or 12 month assessments then their travel will be reimbursed.

Informed Consent and Photo Consent

The study team will seek permission to conduct the interviews first from the village heads, followed by the head of the house hold, and then the participants themselves, or their caretakers if the child is under the age of 18. Participants aged 18 years or more will be asked to complete the informed consent form after reading/ hearing the information provided on the information sheet (Appendix 7 and 8). If necessary, the information sheet will be read aloud, and a thumb print will be taken in place of a signature As well as this thumb print, an independent witness will be asked to sign the informed consent form, this person will be anyone that patient identifies as trustworthy and easy to access for research team (another

caretaker, friend, family member). We will approach this person and ask together with person in question whether they would be comfortable that they act as their witness.
If patients are between the ages of 7 and 18, assent will be sought from the patient themselves (Appendix 9) but this same process of informed consent will be followed from the caretakers of the underage patients. Written informed consent for taking photographs will also be requested. The information and informant consent and assent forms as well as the picture taking consent form will be in Hausa, for the purposes of this protocol they are in English, they will be translated before study implementation. If participants turn 18 during the course of the study, they will be re-consented as adults.

A request will be made during the informed consent process for the researchers to access the medical files of the patients. If this is denied, accessing of files will not progress.

Full information about the purpose and uses of participants' contributions as well as clarification of how contributions will be shared will be explained during the informed consent process as well as the photo consent (Appendix 10). Participants will be assured that participation is in no way associated with the care they will receive at the hospital, and that everything shared will be stored anonymously and nothing will be able to be traced back to them personally.

Data protection and management

All data including names of patients, caretakers and their contact details will remain confidential and will only be available in a password protected database at the Sokoto project base to which only certain authorized staff will have access. Although the results of this study may be published, no information that could identify any of the participants will be included. All reports and publications will refer only to anonymous data. Nominal data will not be distributed outside the study location or appear in any report or publication.

Community engagement

Since 2015, MSF has been working on Noma in the MSF Noma Children's Hospital, however MSF's activities in northwest Nigeria pre date this year substantially. MSF's connection to the community, specifically for Noma, is slowly increasing as the project develops. To date it has focused mostly on active case finding for Noma through established health centres and by spreading messages by radio to inform the population of our existing surgical activities for Noma.

MSF's ongoing community engagement strategy is to target health providers in public health centres and nutrition centres and hospitals focusing on prevention, early detection, treatment and referral. Community leaders, traditional healers and community members are met and the MSF projects are discussed. Noma hospital patients, caretakers as well as beneficiaries from other MSF projects and the general population in the catchment area are involved with the dissemination of health promotional material. Surveillance to understand the prevalence of Noma cases in MSF areas of operations in coordination with a surveillance team is conducted.

The Ministry of Health, who are partners in the study, supports in various ways to address this neglected disease. The PI will visit the program site before project implementation to inform the community about the project. The visit will include a presentation about the project

at the hospital to project staff to discuss the overall aim of the project and the logistical arrangements for the project, a meeting with the Ministry of Health and UDUTH Ethics Chairperson to inform them that the project is being formulated and that the protocol will be submitted for review.

The collaboration between MSF, the Ministry of Health, MSF Noma Children's Hospital and the Usman Danfodiyo University Teaching Hospital will strengthen these relationships, and increase MSF's credibility with these institutions.

Impact on policy and practice

At a project level, the findings will be utilised when planning clinical care, improving routine data collection and improving follow up and outcome assessments. At a policy level, MSF are currently working with the Ministry of Health to make Noma a key health care issue, and as such, these findings could potentially assist in this endeavour. At a global level, there is very little research on Noma and this research will add to the scant body of literature available.

Expected outcomes

Expected outcomes for the project are as follows:

- An estimation of the post discharge survival rate of Noma patients
- As estimation of factors associated with survival of Noma patients which will allow for these factors to be focussed on during care provision so as to optimise survival rates and positive outcomes
- An estimation of outcomes of previously cared for Noma patients
- The creation of a surgical outcome measurement system which will enable ongoing assessment of outcomes of interventions. This system will facilitate a better understanding of the outcomes of the program and allow for monitoring and evaluation of the program to assess effectiveness. The program will also offer potential insights into changes that could be made for ongoing improvement of care provision.
- Strengthening of routine data collection by conducting refresher training and clear briefings of all medical teams. Particularly, the data collection around previous medical history, vaccination history, surgical interventions, surgical/anaesthesia and post-surgical complications and status of patient at discharge will be improved.

Potential limitations

As a part of this project is based on a retrospective review, a big limitation is that if the information is not in the paper medical charts and not already in the database, there will be no way of going back and gathering this data. This will mean insights into the patient population will be limited to the information we have in the charts or database.

This project focus mostly on clinical outcomes of surgery, we do understand the need for assessments on other factors as well, including a qualitative assessment of the impact of the

care provided, and quality of life, however, unfortunately logistical and budget constraints do not allow for such an assessment as part of this project.

Noma has a reported 90% mortality rate, meaning that those seeking treatment are not only a small portion of patients who have developed the disease, they are also the portion of the Noma population which had the least severe complications from the disease. As such, the information gathered will only be a part of this small group and thus results could differ in comparison to those who never accessed care at the Noma Children's Hospital.

The project is being conducted in a high security risk area where the project takes place, which could potentially make travelling to villages to conduct assessments difficult, this may impact upon the number of possible assessments. Not all patients come from states close to the Noma Children's Hospital, and thus could further minimise the number of patients that long term follow up is possible with.

Dissemination of study results

A protocol for collection of data and appropriate follow up (post discharge) will be drafted as a result of this work.

An Internal MSF report will be drafted addressing the main study objectives. This report will be shared with Noma project staff and collaborating MoH health care staff for their information and application of the lessons learnt.

A manuscript will be submitted to a peer review journal on the study in order to continue the medical advocacy around this neglected disease.

Timeline

- March 2018: Submit protocol for MSF ERB approval
- March 2018: Submit for Usman University and Nigerian MoH approval in Sokoto
- May – June 2018: Collect Data for Retrospective
- July - August: Analyse retrospective data and write manuscript
- September – October: Work with co-authors to finalise manuscript
- November 2018: Submit manuscript to journal
- June 2018 – June 2019: recruit new admissions to the study
- June 2018 – December 2020: Follow up with patients at set time points
- January – March 2021: Analyse prospective data and if applicable, write up manuscript

Budget

As this is part of MSF activities, some costs are included in the programmatic costs, and some costs are allocated for in a separate Noma Operational Research Budget.

Table 4- Budget

Estimated Budget for Noma Outcome Survey

*Based on retrospective data collection NOT prospective data collection as that will form part of outreach team activities
*Data entry for 40 Days/ 2 months
*Sample size 106, 3 villages per day, 2 teams, 20 working days

	No. Units	*no. of days*	*Unit Information*	*Total in Naira/ Euro*	*Total in Euro(0.0023)*
Section A - Staff costs					
Research assistant for retrospective chart review (Chart review for 40 Days/ 2 months)	1	40	NGN 6412 per day	NGN 256,480	EUR 589.90
Study Supervisor for retrospective outcome assessments (2 teams of 2 people for 20 days)	1	20	NGN 11828 per day	NGN 236,560	EUR 544.09
Research assistants for retrosepctive assessments (2 teams of 2 people for 20 days)	4	20	NGN 6412 per day	NGN 512,960	EUR 1,179.81
Total Section A					EUR 2,313.80
Section B - Travel and accommodation					
International Flights to and from Sokoto for PI	NA	1		Paid direct in Euro	EUR 1,500.00
Insurance costs	NA	1		Paid direct in Euro	EUR 100.00
Visa costs	NA	1		Paid direct in Euro	EUR 500.00
Total Section B					EUR 2,100.00
Section C - Field study materials					
MSF identification armbands	6	NA	2 Euro per piece	Paid direct in Euro	EUR 12.00
Camera- Sony Cybershot HX300	2	NA	400 Euro each	Paid direct in Euro	EUR 800.00
2 Terabyte Hard drive for back up of pics and data	1	NA	75 Euro each	Paid direct in Euro	EUR 75.00
Training days (refreshments and materials)	2	2	NGN 44,000	NGN 44,000	EUR 100.00
Cars and fuel	2	20	NGN 45 000 a day	NGN 1,800,000	EUR 4,140.00
Drivers	2	20	NGN 3761 per 8 hour day	NGN 150,440	EUR 346.01
Driver over time	NA	3	NGN 50 000 potential over time payment	NGN 150,000	EUR 345.00
Daily water for study teams	6	20	NGN 325 per bottle	NGN 39,000	EUR 89.70
Photocopies consent forms and information sheets (5 pages per form, 120 copies)	120	NA	NGN 10 per page	NGN 6,000	EUR 13.80
Pens	6	NA	NGN 1500 for 100	NGN 1,500	EUR 3.45
Clipboard	4	NA	NGN 300	NGN 1,200	EUR 2.76
Ink pad for thumbprints	2	NA	NGN 300	NGN 600	EUR 1.38
Plastic folder (for protection of questionnaires against rain and dust)	4	NA	NGN 15000 for 10	NGN 15,000	EUR 34.50
Total Section C					EUR 5,963.60
TOTAL BUDGET ESTIMATE					EUR 10,377.40

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Appendices

Appendix 1- Retrospective Assessment Tool

Patient Hospital ID: _____ Date of Assessment: __/__/____

Date of patient's final surgery: __/__/____

Assessment: 6 months 12 months

Name of assessor:

_____

Is the patient still alive	Yes	**If No, complete Verbal Autopsy Form Consent and if given, Verbal Autopsy Form**
	No	

Metrics (to measure WHZ, weight for height and weight for age)
Weight: _____ (kg)
Height: _____ (cm)
Age: _____ (round to closest year)

MUAC (for those under 5 years): _____ (mm)

Colour: Red Orange Yellow Green

Maximum mouth opening
Mouth open: _____ (mm)
Mouth closed: _____ (mm)
Maximum mouth opening: _____ (mm)

Mouth opening comments (note here if measurement was taken from alveolar ridges and not incisors):

_____

Comments:

_____

Appendix 2- Verbal Autopsy Form

Form completed by:

_____

Patient Hospital ID Number:

_____

Respondent's relationship with child: _____

Date form is completed (dd/mm/yy) _____/_____/_____

Date of death _____/_____/_____ Estimation of death-date Y/ N

Age at death _____ months/ years (circle)

Location where patient died: Home / Clinic / other (describe)

_____

Other siblings ill/died? Y/ N

Does the respondent have information on the death of the child? Y N (if 'Y' continue below)

Accident or Injury

Did the child die from an accident or injury		Y	N
If yes, what type of injury	Fall	Y	N
	Bite	Y	N
	Assault	Y	N
	Others (specify)		

Symptoms and signs at the time of death

(Circle all the symptoms and signs that the child had in the 7 days prior to death)

General	Fever	Yes	No
	Oral thrush	Yes	No
	Night sweat	Yes	No
	Weight loss	Yes	No
	Skin rash	Yes	No
Nutritional and GI symptoms	Vomiting	Yes	No
	Watery diarrhea	Yes	No
	Bloody diarrhea	Yes	No
	Jaundice	Yes	No
	Oedema	Yes	No

Respiratory	Coughing	Yes	No
	Difficulty breathing	Yes	No
	Wheezing	Yes	No
	Other? _____	Yes	No
Neurological	Bulging fontanel	Yes	No
	Stiff neck	Yes	No
	Fitting	Yes	No
	Loss of conscience	Yes	No
	Adverse event	Yes	No
Other Symptoms	Weakness (to point can no longer stand)	Yes	No
	Ataxia	Yes	No
	Inconsolable crying	Yes	No
	Restlessness	Yes	No
	Decreased play	Yes	No
	Abdominal pain (colicky)	Yes	No
	Anorexia	Yes	No
	Headache	Yes	No
	Numbness	Yes	No
	Change in skin colour	Yes	No

Cause of Death

According to informant, cause of death?

_____

_____

_____

Healthcare Visited

Was treatment sought Y / N

If Yes, where?

Clinic	Y	N	Traditional healer	Y	N
Hospital	Y	N	Drugs bought from pharmacy	Y	N

Diagnosis

Was a diagnosis given by a clinician? Y / N

If yes- clinician's summary and differential diagnoses:

_____

_____

_____

Appendix 3- Prospective Surgical Outcome Measurement Tool

Patient Hospital ID: _____ Date of Assessment: __/__/____

Date of patients final surgery: __/__/____

Assessment: Admission Pre-operative Discharge from last surgery

6 month post op 12 month post op

Name of assessor:

_____

Is the patient still alive	Yes
	No

If No, complete Verbal Autopsy Form Consent, and if given, complete Verbal Autopy Form

Metrics (to measure WHZ, weight for height and weight for age)
Weight: _____ (kg)
Height: _____ (cm)
Age: _____ (round to closest year)

MUAC (for those under 5 years): _____ (mm)

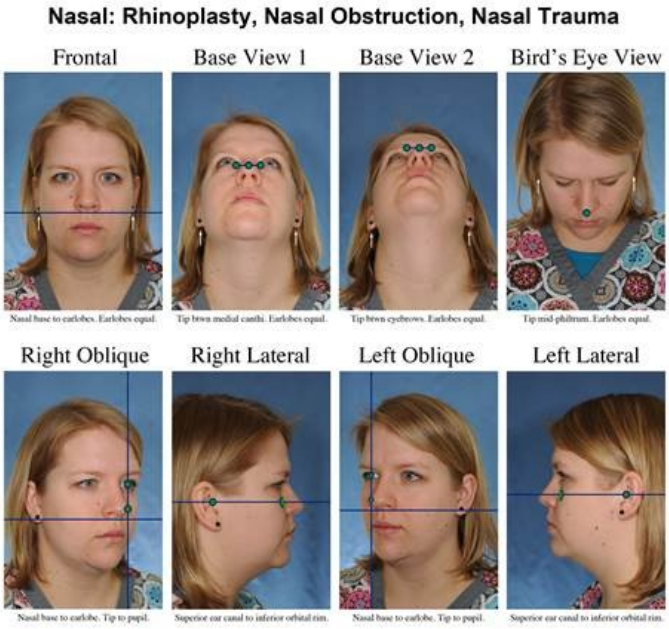
Colour: Red Orange Yellow Green

Maximum mouth opening

Mouth open: _____ (mm)
Mouth closed: _____ (mm)
Maximum mouth opening: _____ (mm)
Mouth opening comments (note here if measurement was taken from alveolar ridges and not incisors):

_____
_____
_____

Pictures to take:



Pictures taken (tick when complete):

Frontal	Base View 1	Base View 2	Bird's Eye View	Frontal close up with mouth open as wide as possible
Right Oblique	Right Lateral	Left Oblique	Left Lateral	Frontal close up with mouth closed (but lips open)

NOITULP Fractional Loss of Anatomical Unit for Noma (surgeons will record)

Fractional *Loss* of Anatomical Unit	
Nose	% Percentage loss
Outer Lining	% Percentage loss
Inner Lining	% Percentage loss
Trismus*	mm mouth opening
Upper Lip	% Percentage loss
Lower Lip	% Percentage loss
Particularities **	No Yes If yes, brief description of particularity:

* Trismus is not an anatomical unit but a functional problem – the inability to open the mouth properly. It has been included in the system because of its clinical relevance (e.g. for intubation).

**Particularities represent pathologic findings pertinent to reconstruction, i.e.: Loss of lower eyelid tissue (Eyelid retraction by a scarred cheek is not to

be noted); Affection of the orbit; loss of an eye is seen quite commonly; Palatal defects; Maxillary sinus defects; Loss of premaxilla; Loss of skin of the chin; Defects of both cheeks.**Patient Self-Reported Outcomes**

Eating and drinking	Food intake	Always Difficult	Sometime Difficult	Easy
	Liquid intake	Always Difficult	Sometime Difficult	Easy

Speech Self Report	People always find it hard to understand what I am saying	Sometimes people don't understand what I am saying	I feel I communicate clearly

Appearance Self-Report	I feel self-conscious about how I look	I sometimes feel good about how I look	I love the way I look

Psychosocial Development	Childs Social Interaction	Less than 1/week	3 - 5 times a week	Every day
	Childs inclusion in communal activities	Less than 1/week	3 - 5 times a week	Every day
	Stigmitisation of child or family	Less than 1/week	3 - 5 times a week	Every day

Comments:

_____

_____

__

Appendix 4- SOP for Mouth Opening Measurement

Mouth opening outcome assessments will be taken in a systematic way. To measure maximum mouth opening, each subject will be asked to sit in a comfortable position, with their heads supported in a natural way. They will be asked to open his or her mouth as wide as possible, while avoiding excessive pain and the examiner will measure the maximum distance from the incisal (cutting) edge of the left maxillary central incisor (tooth in front upper jaw) to the incisal (cutting) edge of the left mandibular central incisor (tooth in front lower jaw) at the midline. The subject will then be asked to close the mouth as far as possible and the same measurement will be taken. The first measurement (mouth open) minus the second measurement (mouth closed) will be the value noted as the maximum mouth opening per subject . The mouth opening will be measured in millimetres with a ruler or sliding callipers.

If the patient is completely edentulous (no teeth) the measurement will be taken from the alveolar ridges (gums). If the patient is missing some teeth but has others, the examiner must use whichever measurement they deem appropriate, with the understanding the goal is to measure functional mouth opening. They will record which measurement was taken under the “comments” section on the data sheet.

Figure 3- Teeth names

(https://areteethbones.com/teeth-names-and-locations-guide-to-communicate-value/)

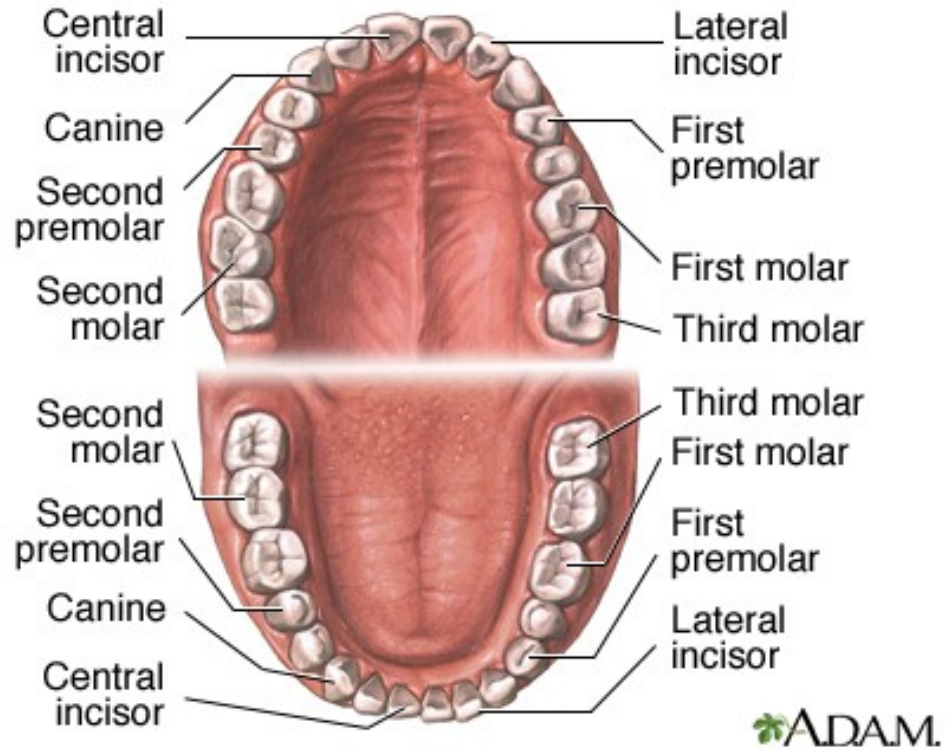


Figure 4- Measuring mouth opening with ruler

(http://www.ijdr.in/article.asp?issn=0970-9290;year=2011;volume=22;issue=3;spage=472;epage=474;aulast=Chaudhary)

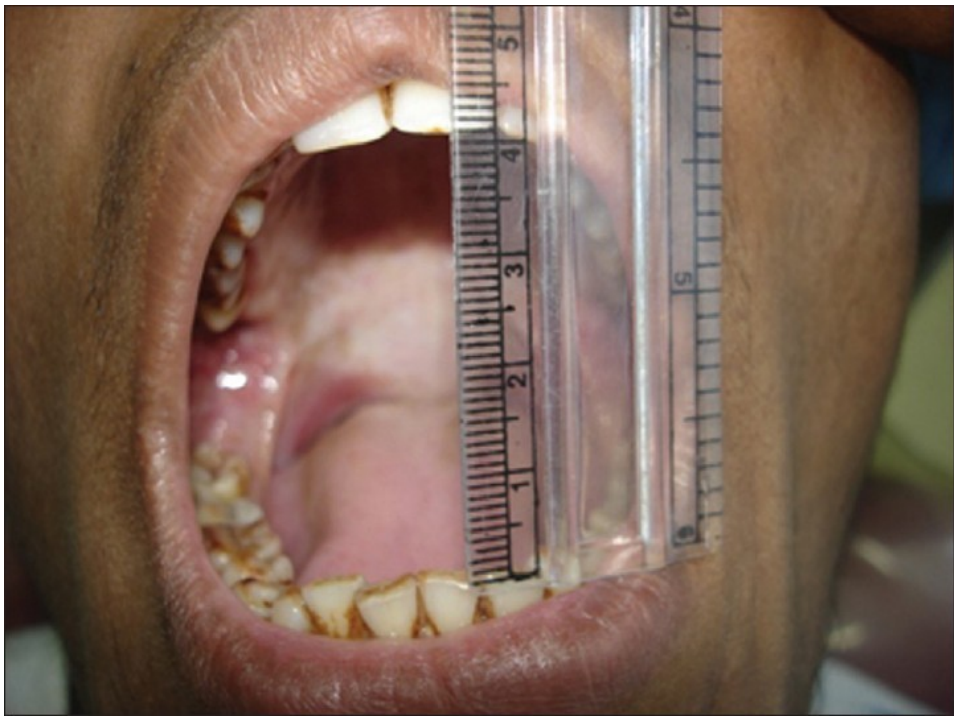
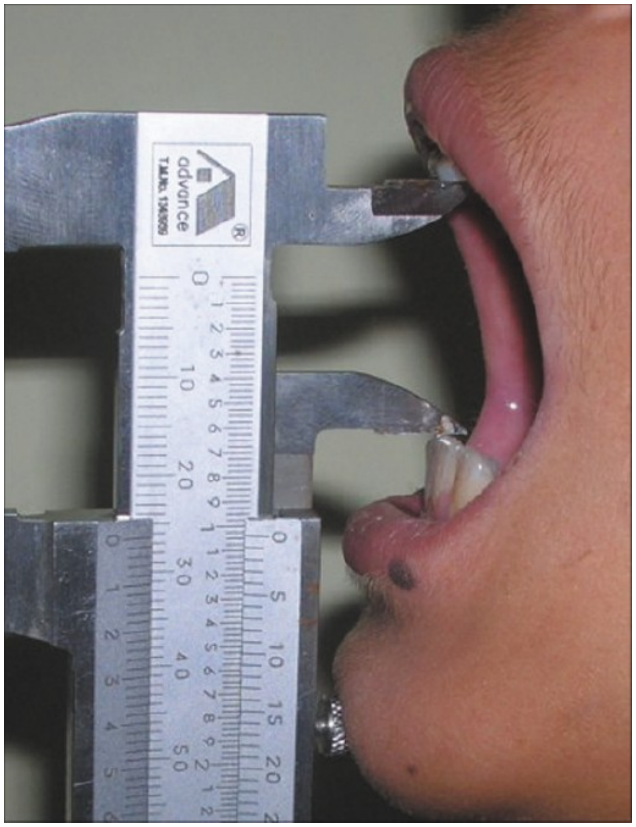


Figure 5- Measuring mouth opening with a caliper

(http://www.jisppd.com/article.asp?issn=0970-4388;year=2012;volume=30;issue=1;spage=85;epage=88;aulast=Dhariwal)



Appendix 5- SOP for Outcome Picture Taking

Pictures for the outcome assessments will be taken in a systematic way.

All pictures will be taken against a blue background (a cloth hung up as a background), where possible, pictures should be taken in direct sunlight without using a flash. Lighting must be sufficient to show in detail the skin surface features and shadows in dark skinned patients. All pictures will be identified by holding a sign with the MSF patient number in the frame of the photograph.

The following views are needed (one set with mouth open and one set with mouth closed):

- Frontal for identification
- Base View 1
- Base View 2
- Birds Eye View
- Right Oblique
- Right Lateral
- Left Oblique
- Left Lateral
- Frontal close up with mouth open as wide as possible
- Frontal close up with mouth closed (but lips open)

The tool below is one used for Rhinoplasty, Nasal Obstruction and Nasal Trauma, and in the absence of a verified Noma outcome measurement photo SOP, this tool will be used to form the basis of the SOP for the Noma outcome measurement pictures. This tool was chosen as it is standardized worldwide and very familiar to plastic surgeons and maxillofacial surgeons. It also provides multiple view angles of the entire face, allowing assessment in multiple dimensions of anatomical areas affected by Noma reconstruction.

Figure 6- Rhinoplasty, Nasal Obstruction and Nasal Trauma Picture Guide

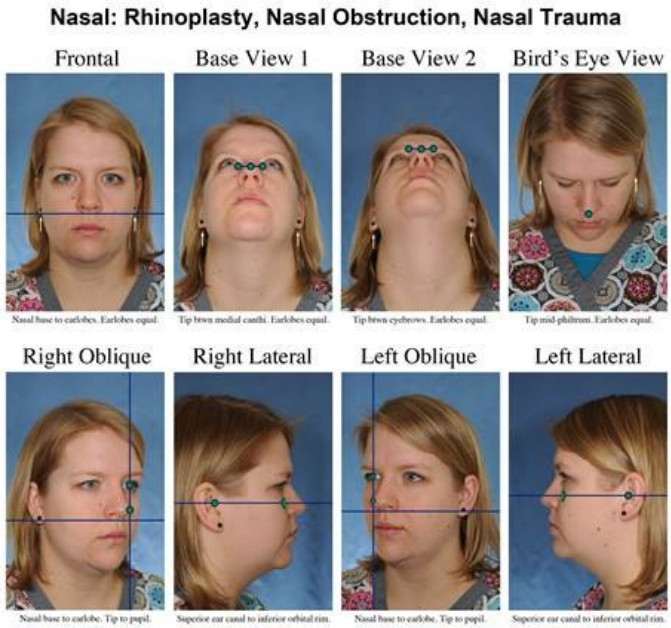


Figure 7- Example Pictures Mouth Open and Mouth Closed

All patient photos will be stored only on the Data Entry Computer and the back-up hard drive, as well as on the MSF telemedicine platform (with restricted access to only those surgeons who are evaluating the pictures). The taking, storage, and dissemination of photos will be as follows:

- Each patient should sign a consent form for having photos taken (Appendix 7). It should be scanned and filed with the photos taken. File name photo consent- Date (in the format dd-mm-yyyy). It should be stored by date as multiple consents may be signed by one patient.
- The data entry officer will be in charge of ensuring that the photos taken are filed under patient number in her computer. The file shall be created under D: my documents: Medical: Patient Data: Photos: (patient number is the file name): then the pictures will be saved/labelled by patient number and date (format: dd-mm-yyyy). More than one photo can be taken on a certain day so the picture will also be labelled with the view consecutively.

  For example: Patient number: 00001, if the picture is taken January 1st, 2018 will be saved as:
  00001-01-01-2018-Frontal
  If a second picture is being taken on the same date:
  00001-01-01-2018-Frontal mouth open

- If a person is requesting to use a photo for a presentation or research they should have signed the proper management of photos form provided by HQ. They will be given specific photos requested only.

Appendix 6: Confidentiality and Non-Disclosure Agreement

Confidentiality and Non-Disclosure Agreement

Project title - Long term follow up of Noma patients after surgical, nutritional and mental health interventions at the Noma Children's Hospital in northwest Nigeria, 2018

I, _____
(name) , the

_____

have been hired to (job title)

_____

_____ (specific job description, e.g., interpreter/translator)

I agree to:

- Keep all the research information shared with me confidential by not discussing or sharing the research information in any form or format (e.g., disks, tapes, transcripts) with anyone other than the *Principal Investigator*.

- Keep all research information in any form or format (e.g., disks, tapes, transcripts) secure while it is in my possession.

- Return all research information in any form or format (e.g., disks, tapes, transcripts) to the *Principal Investigator* when I have completed the research tasks.

- After consulting with the *Principal Investigator,* erase or destroy all research information in any form or format regarding this research project that is not returnable to the *Researcher(s)* (e.g., information stored on computer hard drive).

(Print Name)		(Signature)
	(Date)	

Principal Investigator

Elise Farley		
(Print Name)		(Signature)
	(Date)	

The plan for this study has been reviewed for its adherence to ethical guidelines and approved by Research Ethics Board - *MSF, UDUTH and Ministry of Health in Sokoto and Kebbi States*. For

questions regarding participant rights and ethical conduct of research, contact Dr. Nma Jiya, Address: Usman Danfodiyo University Teaching Hospital, Phone: +234 805 038 1688.

Appendix 7- Information Sheet and Informed Consent for Retrospective Outcome Measurement

Project Title: Long term follow up of Noma patients after surgical, nutritional and mental health interventions at the Noma Children's Hospital in northwest Nigeria, 2018

Organization: Médecins sans Frontières (MSF) and the Ministry of Health

This informed consent has two parts:

1. The information sheet – which gives you information about the study;
2. Certificate of consent study participation – which you will sign to demonstrate that you agree to participate in the assessment for this study;

Introduction

We are conducting this study for Médecins Sans Frontières (MSF) and the Ministry of Health in Sokoto to find out more about the complications after medical treatment for Noma at the Noma Children's Hospital. MSF has been running a program to assist Noma patients in Sokoto Nigeria, and in order to better understand the disease and improve these services, we would like to ask patients and community members some questions.

What is the study about?

Very little is understood about the disease Noma. We are trying to understand what complications arise after treatment for Noma, and what the factors are that favour survival. This information might help MSF and the Ministry of Health to implement programmes to more efficiently and effectively treat Noma patients in the future. During this study, assessments will be conducted on patients who have been treated at the Noma Children's Hospital.

Who will participate in the study?

We will be asking Noma patients who were cared for at the Noma Children's Hospital since 2015 and are not scheduled for follow up surgery to participate in the study.

What does the participation in the study request from me?

As you are a parent/caretaker of a Noma patient or a Noma patient in the Sokoto hospital, we will ask to examine you/ your child. This should take between 10 – 15 minutes.

We will conduct a physical exam to see how you/ your child is/ are healing.

We would like to take some photographs of you to show to some doctors who will then be able to assess how you are healing. If you do not want us to take any photographs, please tell us and we will not take any. We may use these photographs in presentation, reports or in

published articles. If you are not wanting your photograph to be taken, this will not in any way impact the care you receive.

If you do not want to answer a question or if you would like to stop the exam at any time, please tell me as we can stop at any time.

We would also like permission to access your medical files which are stored at the Noma Children's Hospital. This is voluntary and if you would not like us to access your files, this will not in any way impact the care you receive.

I consent to participate in this study (circle): Yes No

I consent to grant the research team access to my medical files (circle): Yes No

Do we have to participate?

Whether you choose to be in the study or not is up to you. There will be no effect on your family or your future treatment at the hospital if you decide you do not want to be in the study.

What will happen with the information that you collect?

The records from this study are private. Only the people who are doing the study can see the answers you give to the questions. I will not repeat what you have told me to anyone else. Once we have the results of this study, we will send an announcement to the health clinics and you will be able to find out what our conclusions are. The pictures we are taking will be stored in a secure folder and only the surgeons assessing the pictures and selected research staff will have access to these. It may be necessary to use your picture in a publication, if you consent to this use. You are free to say no.

Where will the study take place?

We can conduct the assessment anywhere where you feel comfortable: in your house, at the clinic, anywhere else in the village.

Will I or my family receive anything to participate?

You will not get anything, such as money or extra food, for taking part in this survey.

What are the risks of participating in the study?
You may find the physical exam uncomfortable. Stopping the assessment does not impact on the future medical care that MSF may provide for you.

Will I or my family receive anything to participate?

There are no direct benefits to the individual. You will not get anything, such as money or extra food, for taking part in this survey.

Will I be told about the results of the study?
Once we have the results of this study, we will send an announcement to the health clinics and you will be able to find out what our conclusions are. We hope that the results will help

us better understand Noma and contribute to finding better ways to prevent and treat this disease in your community.

Confidentiality:

The records from this study are private. Only the people who are doing the study can see the assessment results. I will not repeat what you have told me to anyone else. Answers from everyone who participates in the study will be grouped together and looked at and it is these findings that will be published, not your specific answers.

Approvals:
The ethical aspects of this research have been approved by Médecins Sans Frontières Ethics Review Committee and by the Usman Danfodiyo University Teaching Hospital (UDUTH) Health Research and Ethics Committee.

Thank you very much for your time and participation.

CONSENT CERTIFICATE ADULT STUDY PARTICIPANT – COPY STUDY TEAM

Please administer the information sheet before seeking consent!

I have understood the information sheet and my questions have been answered to my satisfaction. I give voluntary consent to be a part of the assessment. I understand that I can stop the assessment at any time.

I hereby declare that I consent to the above.

Date: ¦__¦¦__¦ / ¦__¦¦__¦ / ¦__¦¦__¦ *[insert day/month/year of the study]*

Name of Study Participant (≥18 years):

_____

Study Participant signature/ thumbprint: _____

If necessary, name and signature of witness: _____

Assessor's name: _____

Assessor's signature: _____

CONSENT CERTIFICATE ADULT STUDY PARTICIPANT – COPY STUDY PARTICIPANT

Please administer the information sheet before seeking consent!

I have understood the information sheet and my questions have been answered to my satisfaction. I give voluntary consent to be a part of the assessment. I understand that I can stop the assessment at any time.

I hereby declare that I consent to the above.

Date: ¦__¦¦__¦ / ¦__¦¦__¦ / ¦__¦¦__¦ *[insert day/month/year of the study]*

Name of Study Participant (≥18 years):

_____

Study Participant signature/ thumbprint: _____

If necessary, name and signature of witness: _____

Assessor's name: _____

Assessor's signature: _____

Queries and Concerns:

You can call and speak to us at any time if you want to find out more about this research project. Principal Investigator: Elise Farley, email: noma-research@oca.msf.org; Phone: 08025737703

Local Ethics Committee Details for questions regarding rights as research participants:

Dr. Nma Jiya, Address: Usman Danfodiyo University Teaching Hospital , Phone: +234 805 038 1688

Appendix 8- Information Sheet and Informed Consent for Prospective Outcome Measurement (6 and 12 months)

Project Title: Long term follow up of Noma patients after surgical, nutritional and mental health interventions at the Noma Children's Hospital in northwest Nigeria, 2018

Organization: Médecins sans Frontières (MSF) and the Ministry of Health

This informed consent has two parts:

1. The information sheet – which gives you information about the study;
2. Certificate of consent study participation – which you will sign to demonstrate that you agree to participate in the assessment for this study;

Introduction

We are conducting this study for Médecins Sans Frontières (MSF) and the Ministry of Health in Sokoto to find out more about the complications after medical treatment for Noma at the Noma Children's Hospital. MSF has been running a program to assist Noma patients in Sokoto Nigeria, and in order to better understand the disease and improve these services, we would like to ask patients and community members some questions and conduct an assessment.

What is the study about?

Very little is understood about the disease Noma. We are trying to understand what complications arise after treatment for Noma, and what the factors are that favour survival. This information might help MSF and the Ministry of Health to implement programmes to more efficiently and effectively treat Noma patients in the future. During this study, assessments will be conducted on patients who have been treated at the Noma Children's Hospital.

Who will participate in the study?

We will be asking Noma patients who were cared for at the Noma Children's Hospital to participate in the study.

What does the participation in the study request from me?

As you are a parent/caretaker of a Noma patient or a Noma patient in the Sokoto hospital we would like to include you in our study. As part of the study we would like to interview you at admission, pre-surgery, discharge after last surgery and at 6 and 12 months after the date of your last surgery.

During these interviews, we will ask you to spend between 15 - 30 minutes answering some questions and being examined.

We will conduct the following examinations:

- Physical exam to see how you are healing

- We would also like to measure the how much you weight and how tall you are (show the scale and measuring tape).
- We would like to take some photographs of you to show to some doctors who will then be able to assess how you are healing. If you do not want us to take any photographs, please tell us and we will not take any. We may use these photographs in presentation, reports or in published articles. If you are not wanting your photograph to be taken, this will not in any way impact the care you receive.

We will ask you questions about the following things:

- Eating and drinking
- Social interaction and inclusion

If you do not understand a question, please ask me to explain it to you. If you do not want to answer a question or if you do want us to conduct a physical exam or if you would like to stop the assessment at any time, please tell me.

We would also like permission to access your medical files which are stored at the Noma Children's Hospital. This is voluntary and if you would not like us to access your files, this will not in any way impact the care you receive.

I consent to participate in this study (circle): Yes No

I consent to grant the research team access to my medical files (circle): Yes No

Do we have to participate?

Whether you choose to be in the study or not is up to you. There will be no effect on your family or your treatment at the hospital if you decide you do not want to be in the study.

What will happen with the information that you collect?

The records from this study are private. Only the people who are doing the study can see the answers you give to the questions. I will not repeat what you have told me to anyone else. Once we have the results of this study, we will send an announcement to the health clinics and you will be able to find out what our conclusions are. The pictures we are taking will be stored in a secure folder and only the surgeons assessing the pictures and selected research staff will have access to these. It may be necessary to use your picture in a publication, if you consent to this use. You are free to say no.

Where will the study take place?

We can conduct the assessment anywhere where you feel comfortable: in your house, at the clinic, anywhere else in the village.

Will I or my family receive anything to participate?

There are no direct benefits to the individual. You will not get anything, such as money or extra food, for taking part in this survey.

What are the risks of participating in the study?

You may find some questions upsetting and the physical exam uncomfortable. If a question makes you uncomfortable, we can skip this question and go on to the next question, of if you want to stop the physical exam, we can at any time. Stopping the questionnaire does not impact on the medical care that MSF will provide for you.

What might we get from this study?
Once we have the results of this study, we will send an announcement to the health clinics and you will be able to find out what our conclusions are. We hope that the results will help us better understand Noma and contribute to finding better ways to prevent and treat this disease in your community.

Confidentiality:

The records from this study are private. Only the people who are doing the study can see the answers you give to the questions. I will not repeat what you have told me to anyone else. Answers from everyone who participates in the study will be grouped together and looked at and it is these findings that will be published, not your specific answers.

Approvals:
The ethical aspects of this research have been approved by Médecins Sans Frontières Ethics Review Committee and by the Usman Danfodiyo University Teaching Hospital (UDUTH) Health Research and Ethics Committee.

Thank you very much for your time and participation.

CONSENT CERTIFICATE ADULT STUDY PARTICIPANT – COPY STUDY TEAM

Please administer the information sheet before seeking consent!

I have understood the information sheet and my questions have been answered to my satisfaction. I give voluntary consent to answer all the questions in the questionnaire about me/ the child in my care and to undergo a physical examination. I understand that I can stop the assessment at any time.

I hereby declare that I consent to the above.

Date: ¦__¦¦__¦ / ¦__¦¦__¦ / ¦__¦¦__¦ *[insert day/month/year of the study]*

Name of Study Participant (≥18 years):

_____

Study Participant signature/ thumbprint: _____

If necessary, name and signature of witness: _____

Assessor's name: _____

Assessor's signature: _____

CONSENT CERTIFICATE ADULT STUDY PARTICIPANT – COPY STUDY PARTICIPANT

Please administer the information sheet before seeking consent!

I have understood the information sheet and my questions have been answered to my satisfaction. I give voluntary consent to answer all the questions in the questionnaire about me/ the child in my care and to undergo a physical examination. I understand that I can stop the assessment at any time.

I hereby declare that I consent to the above.

Date: ¦__¦¦__¦ / ¦__¦¦__¦ / ¦__¦¦__¦ *[insert day/month/year of the study]*

Name of Study Participant (≥18 years):

_____

Study Participant signature/ thumbprint: _____

If necessary, name and signature of witness: _____

Assessor's name: _____

Assessor's signature: _____

Queries and Concerns:

You can call and speak to us at any time if you want to find out more about this research project.

Principal Investigator: Elise Farley, email: noma-research@oca.msf.org; Phone: 08025737703

Local Ethics Committee Details for questions regarding rights as research participants:

Dr. Nma Jiya, Address: Usman Danfodiyo University Teaching Hospital, Phone: +234 805 038 1688

Appendix 9- Assent Form for any Under 18's

Project Title: Outcomes of Noma patients following surgical, nutritional and mental health interventions at the Noma Children's Hospital in northwest Nigeria, 2018

Organization: Médecins sans Frontières (MSF) and the Ministry of Health

This informed assent has two parts:

3. The information sheet – which gives you information about the study;
4. Certificate of assent study participation – which you will sign to demonstrate that you agree for you to participate in this study;

Information Sheet Child Assent - Copy Study Team

Introduction

My name is _____ and I work for the organization Médecins sans Frontières (MSF) here in Nigeria. We are working hard to reduce the number of cases of Noma in your community and are now doing a study to help us better understand how we can best treat those people who do have Noma.

We have already spoken to the head of your household and have also asked your parents for their approval to speak to you and ask you to help us in this study. We will now give you some information about the study and what it would mean for you to participate. You do not have to agree to participate if you do not want to, even if your parents agreed.

You may discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately.

There may be some words you don't understand or things that you want me to explain more about because you are interested or concerned. Please ask me to stop at any time and I will take time to explain).

What is the study about?

Very little is understood about the disease Noma. We are trying to understand what problems arise after treatment for Noma, and what the things help keep people alive. This information might help MSF and the Ministry of Health to implement programmes to more efficiently and effectively treat Noma patients in the future. During this study, exams will be conducted on patients who have been treated at the Noma Children's Hospital.

Who will participate in the study?

We will be asking Noma patients who were cared for at the Noma Children's Hospital to participate in the study.

Do I have to do this?

Whether you choose to be in the study or not is up to you. There will be no effect on your treatment at the hospital if you decide you do not want to be in the study.

Check that the child understands what you are telling them by asking: "Do you have any questions at this point? Do you understand that you do not have to participate in the study if you do not want to?

I have checked with the child and they understand that participation is voluntary:

_____ **(initial of study interviewer)**

What is going to happen to me?

As you are a patient who was cared for at the Noma Children's Hospital we would like to conduct some examinations and also ask you/ your caretaker some questions. We would also like to take some photographs of you.

We will conduct the following examinations:

- Physical exam to see how you are healing
- We would also like to measure the how much you weight and how tall you are (show the scale and measuring tape).
- We would like to take some photographs of you to show to some doctors who will then be able to assess how you are healing. If you do not want us to take any photographs, please tell us and we will not take any. We may use these photographs in presentation, reports or in published articles. If you are not wanting your photograph to be taken, this will not in any way impact the care you receive.

We will ask you questions about the following things:

- Eating and drinking
- Social interaction and inclusion

If you do not understand a question, please ask me to explain it to you. If you do not want to answer a question or if you do want us to conduct a physical exam or if you would like to stop the exam at any time, please tell me.

Check that the child understands what you are telling them by asking: "Can you repeat to me what you remember from me telling you about what will happen to you as part of this study?

I have checked with the child and they understand that procedures of the study:

_____ **(initial of study interviewer)**

Is it bad or dangerous for me or will it hurt?

You may find some questions upsetting and the physical exam uncomfortable. If a question makes you uncomfortable, we can skip this question and go on to the next question, of if you want to stop the physical exam, we can at any time. Stopping the questionnaire does not impact on the medical care that MSF will provide for you.

Check that the child understands what you are telling them by asking: "Do you understand what could be uncomfortable today when we examine you? Can you repeat it back to me?

I have checked with the child and they understand that risks and discomforts of the study:

_____ **(initial of study interviewer)**

Is there anything good that I might happen to me from this study?

You will not get anything extra like food or money for participating in this study. You are free to stop at any time during the interview.

I have checked with the child and they understand the benefits of the study:

_____ **(initial of study interviewer)**

Is everyone going to know about this and will you tell me the results?

The records from this study are private. Only the people who are doing the study can see the answers you give to the questions. I will not repeat what you have told me to anyone else. Answers from everyone who participates in the study will be grouped together and looked at and it is these findings that will be published, not your specific answers.

Once we have the results of this study, we will send an announcement to the health clinics and you will be able to find out what our conclusions are. We hope that the results will help us better understand Noma and contribute to finding better ways to prevent and treat this disease in your community.

I have checked with the child and they understand that that there is no remuneration for participating in the study and that their information will be kept confidential:

_____ **(initial of study interviewer)**

What happens if I get hurt?

We do not think that you will get hurt today, but in case you don't feel well today or later, you can always ask to be referred and we will try and take care of you as best as possible.

Can I withdraw or refuse to participate?

Whether you choose to be in the study or not is up to you. There will be no effect on your family if you decide you do not want to be in the study.

Who can I talk to if I have a question?

I will give you copy of the information we have talked about today and this has my information on it, so you can always come and find me or contact me in case you have other questions.

I have checked with the child and they understand what to do if they are hurt, that they can withdraw/refuse to participate at any time and how to contact us if they have more questions:

_____ **(initial of study interviewer)**

Queries and Concerns:
You can call and speak to us at any time if you want to find out more about this research project.

Local Ethics Committee Details for questions regarding rights as research participants:

Dr. Nma Jiya, Address: Usman Danfodiyo University Teaching Hospital, Phone: +234 805 038 1688

The ethical aspects of this research have been approved by Médecins Sans Frontières Ethics Review Committee and by the Usman Danfodiyo University Teaching Hospital (UDUTH) Health Research and Ethics Committee.

Thank you very much for your time and participation.

Information Sheet Child Assent - Copy Child Participant

Introduction

My name is _____ and I work for the organization Médecins sans Frontières (MSF) here in Nigeria. We are working hard to reduce the number of cases of Noma in your community and are now doing a study to help us better understand how we can best treat those people who do have Noma.

We have already spoken to the head of your household and have also asked your parents for their approval to speak to you and ask you to help us in this study. We will now give you some information about the study and what it would mean for you to participate. You do not have to agree to participate if you do not want to, even if your parents agreed.

You may discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. You can decide whether to participate or not after you have talked it over. You do not have to decide immediately.

There may be some words you don't understand or things that you want me to explain more about because you are interested or concerned. Please ask me to stop at any time and I will take time to explain).

What is the study about?

Very little is understood about the disease Noma. We are trying to understand what problems arise after treatment for Noma, and what the things help keep people alive. This information might help MSF and the Ministry of Health to implement programmes to more efficiently and effectively treat Noma patients in the future. During this study, exams will be conducted on patients who have been treated at the Noma Children's Hospital.

Who will participate in the study?

We will be asking Noma patients who were cared for at the Noma Children's Hospital to participate in the study.

Do I have to do this?

Whether you choose to be in the study or not is up to you. There will be no effect on your treatment at the hospital if you decide you do not want to be in the study.

Check that the child understands what you are telling them by asking: "Do you have any questions at this point? Do you understand that you do not have to participate in the study if you do not want to?

I have checked with the child and they understand that participation is voluntary:

_____ **(initial of study interviewer)**

What is going to happen to me?

As you are a patient who was cared for at the Noma Children's Hospital we would like to conduct some examinations and also ask you/ your caretaker some questions. We would also like to take some photographs of you.

We will conduct the following examinations:

- Physical exam to see how you are healing
- We would also like to measure the how much you weight and how tall you are (show the scale and measuring tape).
- We would like to take some photographs of you to show to some doctors who will then be able to assess how you are healing. If you do not want us to take any photographs, please tell us and we will not take any. We may use these photographs in presentation, reports or in published articles. If you are not wanting your photograph to be taken, this will not in any way impact the care you receive.

We will ask you questions about the following things:

- Eating and drinking
- Social interaction and inclusion

If you do not understand a question, please ask me to explain it to you. If you do not want to answer a question or if you do want us to conduct a physical exam or if you would like to stop the exam at any time, please tell me.

Check that the child understands what you are telling them by asking: "Can you repeat to me what you remember from me telling you about what will happen to you as part of this study?

I have checked with the child and they understand that procedures of the study:

_____ **(initial of study interviewer)**

Is it bad or dangerous for me or will it hurt?

You may find some questions upsetting and the physical exam uncomfortable. If a question makes you uncomfortable, we can skip this question and go on to the next question, of if you want to stop the physical exam, we can at any time. Stopping the questionnaire does not impact on the medical care that MSF will provide for you.

Check that the child understands what you are telling them by asking: "Do you understand what could be uncomfortable today when we examine you? Can you repeat it back to me?

I have checked with the child and they understand that risks and discomforts of the study:

_____ **(initial of study interviewer)**

Is there anything good that I might happen to me from this study?

You will not get anything extra like food or money for participating in this study. You are free to stop at any time during the interview.

I have checked with the child and they understand the benefits of the study:

_____ **(initial of study interviewer)**

Is everyone going to know about this and will you tell me the results?

The records from this study are private. Only the people who are doing the study can see the answers you give to the questions. I will not repeat what you have told me to anyone else. Answers from everyone who participates in the study will be grouped together and looked at and it is these findings that will be published, not your specific answers.

Once we have the results of this study, we will send an announcement to the health clinics and you will be able to find out what our conclusions are. We hope that the results will help us better understand Noma and contribute to finding better ways to prevent and treat this disease in your community.

I have checked with the child and they understand that that there is no remuneration for participating in the study and that their information will be kept confidential:

_____ **(initial of study interviewer)**

What happens if I get hurt?

We do not think that you will get hurt today, but in case you don't feel well today or later, you can always ask to be referred and we will try and take care of you as best as possible.

Can I withdraw or refuse to participate?

Whether you choose to be in the study or not is up to you. There will be no effect on your family if you decide you do not want to be in the study.

Who can I talk to if I have a question?

I will give you copy of the information we have talked about today and this has my information on it, so you can always come and find me or contact me in case you have other questions.

I have checked with the child and they understand what to do if they are hurt, that they can withdraw/refuse to participate at any time and how to contact us if they have more questions:

_____ **(initial of study interviewer)**

Queries and Concerns:

You can call and speak to us at any time if you want to find out more about this research project.

Principal Investigator: Elise Farley, email: noma-research@oca.msf.org; Phone: 08025737703

Local Ethics Committee Details for questions regarding rights as research participants:

Dr. Nma Jiya, Address: Usman Danfodiyo University Teaching Hospital, Phone: +234 805 038 1688

The ethical aspects of this research have been approved by Médecins Sans Frontières Ethics Review Committee and by the Usman Danfodiyo University Teaching Hospital (UDUTH) Health Research and Ethics Committee.

Thank you very much for your time and participation.

Assent Certificate Child Study Participant – Copy Study Team

I have read this information (or had the information read to me) and I have had my questions answered and know that I can ask questions later if I have them.

☐	I agree to take part in the research
☐	I do not wish to take part in the research and have not signed the assent below – Initials of the child _____

Only if child assents:

Print name of child _____

Signature of child: _____

Date: ¦__¦¦__¦ / ¦__¦¦__¦ / ¦__¦¦__¦ *[insert day/month/year of the study]*

If the child is illiterate:

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness (not a parent) _____

Signature of witness _____

Date: ¦__¦¦__¦ / ¦__¦¦__¦ / ¦__¦¦__¦ *[insert day/month/year of the study]*

AND Thumb print of parti

I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Print name of researcher_____

Assent Certificate Child Study Participant – Copy Study Participant

I have read this information (or had the information read to me) and I have had my questions answered and know that I can ask questions later if I have them.

☐	I agree to take part in the research
☐	I do not wish to take part in the research and have not signed the assent below – Initials of the child _____

Only if child assents:

Print name of child _____

Signature of child: _____

Date: ¦__¦¦__¦ / ¦__¦¦__¦ / ¦__¦¦__¦ *[insert day/month/year of the study]*

If the child is illiterate:

A literate witness must sign (if possible, this person should be selected by the participant, not be a parent, and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness (not a parent) _____

Signature of witness _____

Date: ¦__¦¦__¦ / ¦__¦¦__¦ / ¦__¦¦__¦ *[insert day/month/year of the study]*

AND Thumb print of participant

I have accurately read or witnessed the accurate reading of the assent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given assent freely.

Print name of researcher_____

Appendix 10- Informed Consent for Picture Taking

Permission to Use Photograph

Project Title: Outcomes of Noma patients following surgical, nutritional and mental health interventions at the Noma Children's Hospital in northwest Nigeria, 2018

Organization: Médecins Sans Frontières (MSF) and the Ministry of Health

I grant to Médecins Sans Frontières, its representatives and employees the right to take photographs of me/ my child in connection with the above-identified project.

I agree that Médecins Sans Frontières may use the photographs of me/ my child, to assess the outcome of the surgical care provided at the Noma Children's Hospital, in presentation, reports or in published articles. If you are not wanting your photograph to be taken, this will not in any way impact the care you receive. These photos will be uploaded to a secure telemedicine portal, and thereafter deleted from the camera with which they were taken. Once uploaded to the telemedicine portal, only a select few research team members and three independent surgeons will have access to the photographs. They will only be viewed in order to conduct an assessment and not for any other purpose. These photographs will be stored on the telemedicine portal for the next 5 years, after which time they will be deleted unless further outcome assessments will take place, this will be done only with your permission. It may be necessary to use your picture in a publication, if you consent to this use. You are free to say no to this request.

I consent to my pictures being used for the outcome assessments (circle): Yes No

I consent to my picture possibly being used in a publication, presentation or report: Yes No

I have read and understand the above and consent to my picture being taken for the outcome assessment:

Signature/ Thumbprint _____

Printed name _____

Date _____

Signature/ thumbprint of Parent or guardian _____ (if under age 18)

I also consent to my picture possibly being used in a publication, presentation or report:

Signature/ Thumbprint _____

Printed name _____

Date _____

Signature/ thumbprint of Parent or guardian _____ (if under age 18)

Appendix 11 - Verbal Autopsy Informed Consent Form

Project Title: Outcomes of Noma patients following surgical, nutritional and mental health interventions at the Noma Children's Hospital in northwest Nigeria, 2018

Organization: Médecins Sans Frontières (MSF) and the Ministry of Health

Introduction

We are conducting this study for Médecins Sans Frontières (MSF) and the Ministry of Health in Sokoto to find out more about the complications after medical treatment for Noma at the Noma Children's Hospital. MSF has been running a program to assist Noma patients in Sokoto Nigeria, and in order to better understand the disease and improve these services, we would like to ask patients and community members some questions.

What is the study about?

Very little is understood about the disease Noma. We are trying to understand what complications arise after treatment for Noma, and what the factors are that favour survival. This information might help MSF and the Ministry of Health to implement programmes to more efficiently and effectively treat Noma patients in the future. During this study, assessments will be conducted on patients who have been treated at the Noma Children's Hospital.

What is a verbal autopsy?

The verbal autopsy form will ask questions about the signs and symptoms your child experienced before he/ she died. These questions are being asked so we can try and understand why your child died.

We understand this may be upsetting and you do not have to answer any of these questions. If you would like to stop at any time, please tell me so and we will stop the interview.

I understand why I am being asked these questions and I understand I can stop at any time:

Signature/ Thumbprint _____

Printed name _____

Date _____