Assessing the feasibility of preventing injury risks and improving work safety amongst factory workers in an urban slum: a participatory before-and-after intervention study

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Bangladesh 2018

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1. SYNOPSIS

Version 1	**Date 18/01/2018**
Study Title	Assessing the feasibility of preventing injury risks and improving work safety amongst factory workers in an urban slum: a participatory before-and-after intervention study
Study Design	A participatory mixed method 'before and after 'design will be used. Data will be collected through: i) Surveillance (incident/injury registers) implemented in selected factories; ii) MSF occupational health clinic data (routine data) iii) Factory hazard assessment and Industrial Hygienist observation; iv) In-depth interviews (pre- and post-intervention); v) Focus groups discussions (participatory intervention design and evaluation)
Study Participants	Factory managers, owners and workers in two identified metal factories
Planned Sample Size	All workers within the two identified metal factories, depending on the size of selected factories (in Kamrangirchar there is an estimated average of 18 workers per factory)
Planned Study Period	April to December2018
	Objectives
Primary	To assess the feasibility of collaborating with factory workers to implement occupational health interventions to prevent injury risks and ultimately improve work safety
Specific objectives	1. ~~Understand~~ Explain dynamics of injury risk over time by: 1.1. Describing the circumstances of incidents leading to an injury (injury risks or dynamics of incident) 1.2. Describing the circumstances of near-miss incident where no injury or illness occurs (incident risks) 1.3. Measuring frequency and severity of injuries (burden) 1.4. Describe ~~Understanding~~ perceptions of risks amongst owner/manager/ workers 2. Design acceptable interventions to reduce injury risks 3. Document intervention feasibility by: 3.1. Describing acceptability, capturing adherence to interventions and changes in risk perceptions 3.2. Describing practicality: 3.2.1. Documenting operational challenges and lessons learned 3.2.2. Capturing resources (human resources, time, materials and cost) of implementation 4. Describe any changes in worker safety behaviour and incident

	incidence rate	
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Data collection and analysis	MSF-OCA, Manson unit	
Study sponsor	MSF-OCA	

2. LIST OF ABBREVIATIONs

CIPRB	Centre for Injury Prevention and Research, Bangladesh
DGHS	Directorate General of Health Services
DIFE	Department of Inspection for Factories and Establishments
EU	European Union
ICDDR,B	The International Centre for Diarrhoeal Disease Research, Bangladesh
FGD	Focus Group Discussion
FSW	Factory Surveillance Workers
ICF	Informed Consent Form
HCD	Human Centred Design
IR	Injury register
IDI	In-depth Interview
ILO	International Labour Organization
MOHFW	Ministry of Health & Family Welfare
MoLE	Ministry of Labour and Employment
MSF-OCA	**Médecins Sans Frontières Operational Centre Amsterdam**
NIOSH	National Institute for Occupational Safety and Health
OH	Occupational Health
OSHA	**Occupational Safety and Health Administration**
PPE	Personal Protective equipment
SOP	Standard Operating Procedure

3. BACKGROUND

The International Labour Organization (ILO) estimateds in a 2014 report that occupational incidents and work-related diseases cause over 2.3 million fatalities annually, of which over 350,000 are caused by occupational incidents and 2 million by work-related diseases. This means that every day nearly 1,000 people die as a result of occupational incidents, and approximately 860,000 people experience non-fatal occupational incidents (requiring at least four days of absence from work) .

This represents a significant, yet largely preventable, burden of morbidity and mortality, and causes both direct and hidden costs to society as a whole . Workers involved in small-scale manufacturing businesses, as well as those in countries going through rapid industrial progression, particularly in Asia, are particularly vulnerable to these risks . Despite this, occupational health and illness is generally less visible and not adequately recognized as a problem in low-income countries .

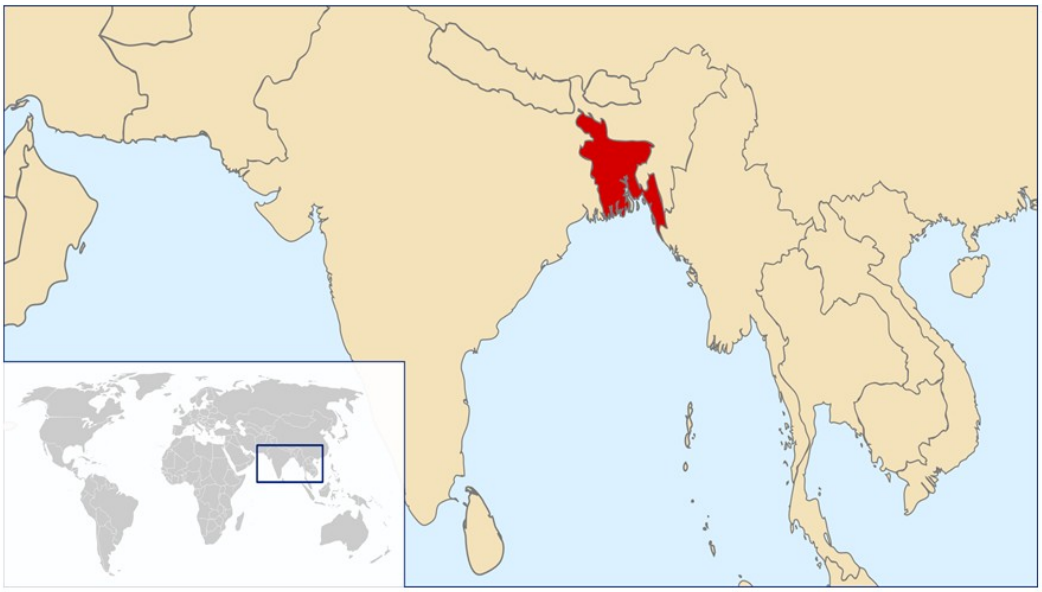
3.1. Context in Bangladesh

Recent decades in Bangladesh have been characterised by economic transformation and rapid urbanisation . Dhaka is one of the world's fastest-growing megacities; much of its expansion has occurred in slums which are now home to around one third of the country's urban population and much of the country's industry [8].

The country has a large working population (52 million; 32.6 million in agriculture, 13.5 million in services, 5.7 million in industry), of which an estimated 88% depends on work in the informal sector . This consists of small-scale often unregistered business units, and is generally characterised by low pay, poor working conditions, absence of social protection and low productivity . Child labour is also considered a major issue, with an estimated 4.7 million or 12.6% of children aged 5 to 14 in the workforce, of which 93% are employed in the informal sector such as small factories and workshops, on the street, in home-based businesses and domestic employment [13].

This is compounded by the absence of a mechanism to support workes rights due diligence in supply chains at different levels.

Figure 1: Map of Bangladesh



Occupational injury in Bangladesh

Existing data indicates that 11.7 thousand workers suffer from fatal incidents and a further 24.5 thousand die from work related diseases across all sectors each year in Bangladesh . Hazards are particularly evident in the case of informal sector workers where the monitoring of safety standards and labour rights are weak to non-existent [8]; data from the Bangladesh Occupational Safety, Health and Environment Foundation (OSHE) show that 72% fatalities and 54% of injuries between January and June 2015 occurred in the informal sector . Young workers are also considered to particularly vulnerable to occupational injury .

Recent industrial incidents have brought global attention to severe occupational health and safety risks in Bangladesh's factories (notably the collapse of Rana Plaza in April 2013 that killed 1,129 workers –one of the worst industrial disasters on record [6]). Occupational injury and disease has been recognised as a public health issue and it has been declared a national priority to be addressed . However, many workers continue to operate in poor working conditions and in the absence of occupational health and safety standards .

Comparatively little research has been undertaken on occupational incidents in Bangladesh and existing data has been criticised as sparse and unreliable . Injury estimates largely come from surveys conducted at household level amongst rural workers , or focus on child labour , and rely on self-reports. There remains a lack of accurate surveillance systems to monitor injuries and under-reporting is problematic (suggested to be due to employers' lack of knowledge of their

reporting obligations; fear of consequences if incidents are reported; and lack of any consequences when incidents are not reported).

Despite international recognition that most occupational deaths and injuries are entirely preventable through basic provisions to reduce hazards and risks, and ensure safer work spaces , there remains a critical lack of interventions to mitigate injury risks at work .

Occupational health legislation in Bangladesh

Bangladesh has not ratified key international labour standards on occupational health and safety policy, namely the Promotional Framework for Occupational Safety and Health Convention, 2006 (No. 187) and the Occupational Safety and Health Convention, 1981 (No.155) .

Key national responsible authorities are the Ministry of Labour and Employment (MoLE) and the Department of Inspection for Factories and Establishments (DIFE).

National legislation with implications for occupational health and injury in Bangladesh are:

- The Bangladesh Labour Act (2006) captures the need of a safe working environment and prescribes employers to take “appropriate measures to protect workers in times of hazardous activities and from the danger and damage of fire” (XVII of 2006 Bangladesh Laws, 2006, p. 42). It requires the employer to provide its workers with pure drinking water, sufficient light and air, and separate toilets for man and women. It also mandates ~~requires~~ factory occupiers to report deaths, injuries and diseases to the Inspectorate of Factories. It extended reporting requirements to a wider range of establishments, including factories employing more than five workers . It also prohibits employment of children under 14 years of age, as well as hazardous forms of child labour for persons under age 18 .
- The Labour (Amendment) Act (2013~~)~~ , enacted following the Rana Plaza collapse (where more than 1,100 garment workers were killed), aimed to bring Bangladeshi labour law more in line with the international standards on working conditions and the environment of workers. It provides various precisions on health and safety measures, including emergency exits; access to gangways and stairs for workers; mandatory use of personal safety equipment; trainings on workplace risks; additional fire prevention and safety measures; notification of competent authority in case of incident; and provisions on social dialogue, trade unions and dispute resolution; and employers and companies’ responsibilities. It also ~~introduces several provisions aimed at improving workplace safety,~~ includ~~inges~~ obligations to create safety committees (in factories with +50 workers); to establish workplace Health Centres (workplaces with +5000 employees); and to arrange for and cover the cost of treatment of occupational diseases (+500 employees). Other important amendments deal with dangerous work for children~~;~~ ~~emergency exits; access to gangways and stairs for workers; mandatory use of personal safety equipment and notification of competent authorities in case of incidents~~ .

Despite recent reforms, current legislation still falls short of international standards.

The Ministry of Labour and Employment has also adopted a National Child Labour Elimination Policy 2010. This defines hazardous work for children as: work for more than five hours a day; that creates undue pressure on physical and psychological wellbeing and development; without pay; and where the child becomes the victim of torture or exploitation or has no opportunity for leisure .

Most of the current legislation targets garment factories and tanneries, and factories employing over 50 workers. As a result metal, plastic and small-scale factories remain without clear legislation, and existing standards remain largely unenforced [REF Amnesty].

1.1.1. ~~Kamrangirchar slum, Dhaka~~

Kamrangirchar, located on the Buriganga River, is one of Dhaka's largest slums, with a population of 440,000 concentrated in an area of 3.68 square kilometres. The settlement grew rapidly during the 1990s with the expansion of the ready-made garment sector and a thriving informal economy . It continues to house a concentration of Bangladesh's small-scale factories, engaged in a variety of activities such as plastic recycling, metal smelting/welding, producing garments, car batteries, toys and balloons. The area borders with the district of Hazaribagh where, until March 2017, 95% of the country's tanneries were located[1].

These factories are often characterised by an absence of minimum safety standards: buildings are poorly maintained and inadequately ventilated, cooled, heated or lit; personal protective equipment is inadequate or absent; workers are often exposed to hazardous materials, chemicals, and/or and are under-informed about related risks and injury prevention; and injury reporting mechanisms are very poor.

Figure 2: Map of Kamrangirchar

1 In March 2017, the tanneries were forced to shift to Savar area where improved facilities for tanner production are under development.

In 2013 Médecins Sans Frontières Operational Centre Amsterdam (MSF-OCA) conducted a survey on occupational risks and morbidity among factory workers . Results revealed a neglected working population with high prevalence of occupational injury (72%) and morbidity in a context of unregulated work conditions and without access to health care.

In 2014 MSF opened five occupational clinics, three in Kamrangirchar, targeting small scale plastic, metal, and garment workers, and two in Hazaribagh targeting tannery workers. MSF established agreements with factory owners/managers to facilitate access to care for workers and foster relationships with owners/managers. Once the agreement is established, factories and their workers are considered 'registered'. However, MSF also provides care to workers in 'unregistered' factories and the local population if they seek care in an MSF clinic. In 2017, the overall number of factories with who MSF set and agreement was 153, every year the list ~~of registered~~of registered factories is update since over time factory might close, move or new factories can set up them self in the area.

-MSF also has an outreach team visiting the factories and tanneries informing the workers about MSF services and providing tetanus vaccination. In 2015 a second occupational survey was implemented in the tannery sector, confirming a high prevalence of occupational injury also among tanneries workers (80%) . _

In addition to occupational health, MSF also provides services for sexual and reproductive health, sexual gender based violence (SGBV), and mental health. These services are integrated with occupational health care.

The team is currently undertaking an mapping of the main supply chain and shareholders involved at different level on the supply chain. This will be used as a frame for sharing study findings and support to build awareness of workers' rights and safety at the different levels.

A critical element of the project's activities and factor for their success has been consistent engagement with factory owners and workers. Regular meetings have been held with factory owners and managers in order to gain their trust and support and MSF outreach workers have maintained a consistent presence in factories (2-weekly visits), ensuring a good contact with workers and supervisors over the last 3 years. This is demonstrated by the high number of MSF registered factories, and the high participation of factories in the hazard assessment (see section 3.2.2). Also several factories that do not have a formal agreement with MSF have started to send their workers to our clinics as a sign of confidence ad trust in our activities.

3.3. Injury burden and factory hazards documented by MSF

3.2.1 Injury burden

In 2017, MSF conducted an in-depth analysis of injury among factory workers attending MSF clinics between 2014 and 2016. This analysis was done overall and by type of factory where patients works.

Of the 5,198 workers that visited MSF clinics, information on past injuries was available for 5,196 and on injuries during the first visit to a MSF clinic for 5,194 workers, respectively. In total, 434 patients had an injury form completed (Table 1). Overall, a~~A~~bout a third of the cases with injuries were minors (<18 years of age), with a median age of 15 (IQR: 12.5-16). For adults, the median age was 25 (IQR: 21-35).

For all factory types, more than 80% of the injuries occurred during the day. For all factory types, the majority (more than 70%) of incidents happened when carrying out routine activities. About half of injuries were caused by sharp objects (47%), followed by blunt objects (21%) and other causes (13.4%). For all factory types, injuries to the hand and wrist were most common (Figure 3).

Metal factories accounted for most injuries (41.7%). Among metal ~~workers 60~~workers 60% of ~~injuries occurred~~injuries occurred in people aged less than 18 years old. ~~-~~Metal workers also experienced the most occupational injury consistent with concussion to the head (13.8%), and 59.1% of injuries were caused by a sharp object.

For 436 workers, information was available on the use of personal protective equipment (PPE) at the moment of injury. Of these, 32 (7.3%) reported to have worn PPE at the time of injury: 8 (9.4%) worked in plastic, 15 (8.3%) in metal, 5 (8.2%) in leather, 1 (4%) in garment and 3 (3.8%) in tannery factories, respectively.

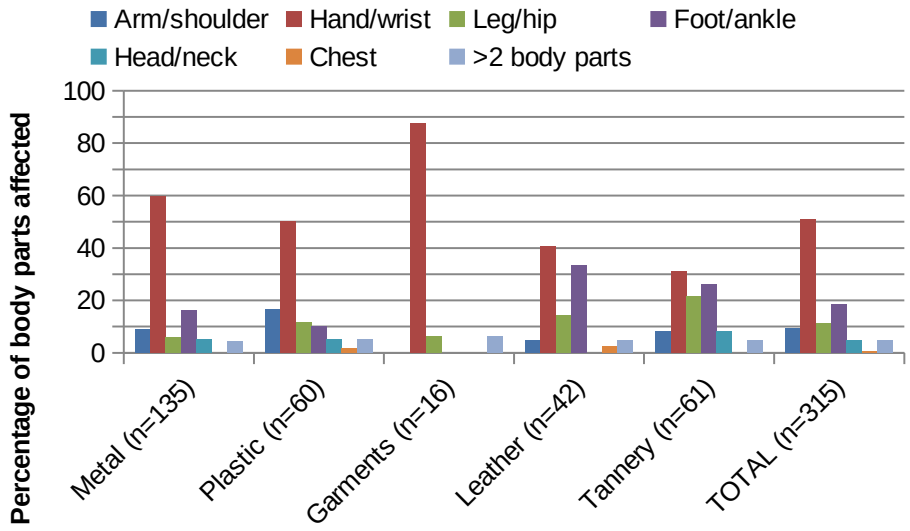
Table 1: Characteristics of workers (N=434[a]) that filled in an injury form between 2014 and 2016

Characteristic	Category	Number	Percent
Age group in years	8-14	52	11.98
	15-24	199	45.85
	25-55	174	40.09

	≥56	9	3.07
Minors	<18 years	120	**27.7**
Adults	>18	314	**72.3**
Sex	Male	373	85.9
	Female	120	14.1
Factory type	Metal	181	41.7
	Plastic	85	20.0
	Garments	25	5.8
	Leather	61	14.1
	Tannery	80	18.4
	Other types	2	0.5

[a] Three individuals that filled in an injury form were not in the database for first consultations, hence no information on demographics was available.

Figure 3: Percentage of body parts affected by the injury by factory type (n=315)



Combined with the findings of the 2013 and 2015 surveys, this analysis indicates that occupational injury is common amongst this working population. Young workers and metal workers experienced the highest burden of injury.

3.2.2 Factory hazard assessment

In early 2017, MSF asked to 153 registered factories to participate ~~to~~in ~~conducted~~ a hazard risk assessment ~~in 151 MSF registered factories~~, with the support of a consultant Industrial Hygienist. This was done in order to evaluate work safety conditions and identify potential areas for improvement in the factory where MSF patients works.

~~The~~The assessment reflects the working conditions of 5,084 tannery, garment, plastic and metal workers; MSF's target population. ~~Overall~~ Overall 151 factory agreed to participate (98%)~~of the factories agreed to participate~~, indicating a good degree of acceptance and trust of the MSF team.

The factory hazard assessment spanned 26 items based on international labour standards, grouped in the following categories:

- General physical safety (e.g. presence of light)
- Control measures (e.g. chemicals stored in closed labeled containers)
- Protective equipment (e.g. hand protection)
- Ergonomics (e.g. remaining in the same position for a prolonged period)

A score was developed to assess the overall work safety performance by calculating the percentage of positively scored questions/ positively assessed items by factory, using all questions with a valid answer (i.e. yes and no- answers) as a denominator.

Almost none of the factories provided safe drinking water for their workers and 78.1% did not have soap. 26.5% of the assessed factories had a functioning fire extinguisher. Almost all the factory types failed to provide safety measures to:

- prevent entanglement through covering moving machine parts or straining loose fitting clothing or hair;
- label and store chemicals in the correct way;
- carry out hot works (e.g. welding, grinding, torch work) away from flammable material;
- effectively remove chemicals dusts and fumes from the workplace.

Almost none of the factories assessed had adequate personal protective equipment available to workers. Similarly, almost all factories failed to provide an ergonomically acceptable working environment. All factories had a very low overall performance score in all areas, indicating a major need to improve safety for workers.

Concerning metal factories,34 participated in the assessment, of which less than 10% had dry and clean floors. 61% of metal factories did not provide enough light to execute the work. Seventy percent did not have a functioning fire extinguisher present. 95% of the metal factories did not haved chemicals stored in closed, labelled containers, and a similar percentage did not had hand protection (e.g. gloves) available for workers. This indicates that metal factories fell far short of both international standards and current Bangladesh legislation.

3.4. Existing literature on occupational injury mitigation interventions

Intervention research is a relatively new promising occupational safety and health research area that is becoming widely accepted as an essential component of occupational safety and health research efforts . Findings of such research can be used to help replicate an intervention that has been shown to be feasible or effective in one context to another setting, and help others adapt an intervention to a new setting while avoiding pitfalls . Several studies have been conducted focussing on reducing injury, showing that injuries can be clearly identified and prevented by making working environments, as well as products and services that workers use, safer .

However, intervention research is generally conducted in ‘developed’ contexts ; there is very little data available on the feasibility and effectiveness of such interventions in the context of rapidly industrialising countries and focussing on the small-scale manufacturing or informal sectors. Research in these contexts generally documents working conditions and occupational health and injury (e.g. amongst workers in metal manufacturing industries in Ethiopia ; in carpet factories in Nepal ; and in a metal auto-parts factory in eastern Thailand) using quantitative surveys. Please see an overview of occupational health intervention research in Annex 1.

4. Rationale ~~Jjustification~~ for the study

Results of MSF surveys show that occupational injuries are among the most frequently reported health issues affecting Kamrangirchar's population. Data from MSF clinics show that workers in metal factories and young workers are particularly vulnerable to injury. The factory ~~hazard assessment~~hazard assessment (section 3.2.2) provided evidence of hazardous working conditions that could explain injury and other morbidities observed among MSF patients, indicating that interventions to improve workplace safety are likely to improve workers' health.

However, this remains a neglected area of public health in Bangladesh, and there is an absence of injury surveillance systems to quantify the real burden and inform appropriate interventions. Moreover, there is currently no action taken to prevent or mitigate the risks of occupational injuries reported by MSF's patients, leaving them continually exposed to hazards and unsafe workspaces. Despite evidence that injuries can be identified and prevented by making working environments, as well as products and services that workers use, safer , currently there is a lack of operational evidence documenting interventions that could reduce injury risk and ultimately improve work safety.

To our knowledge a study has never been carried out aiming to implement interventions to mitigate injury risk amongst this specific working population. As a result, this study provides a unique opportunity to develop an in-depth understanding of injury dynamics amongst workers in Kamrangirchar, as well as to demonstrate if, and how, it is feasible to implement interventions to mitigate injury risk and improve work safety. As per the MSF charter, the study aims to alleviate suffering and restore dignity amongst this marginalised population.

~~Firstly, by designing implementing interventions we aim to increase injury risk awareness, mitigate injury and improve overall work safety, thus improving the health status of workers in selected factories.~~

Secondly, by enabling us to learn about the feasibility of implementing public health interventions inside the workspace, the results will support MSF in developing appropriate medical interventions and advocacy strategies for this neglected population.

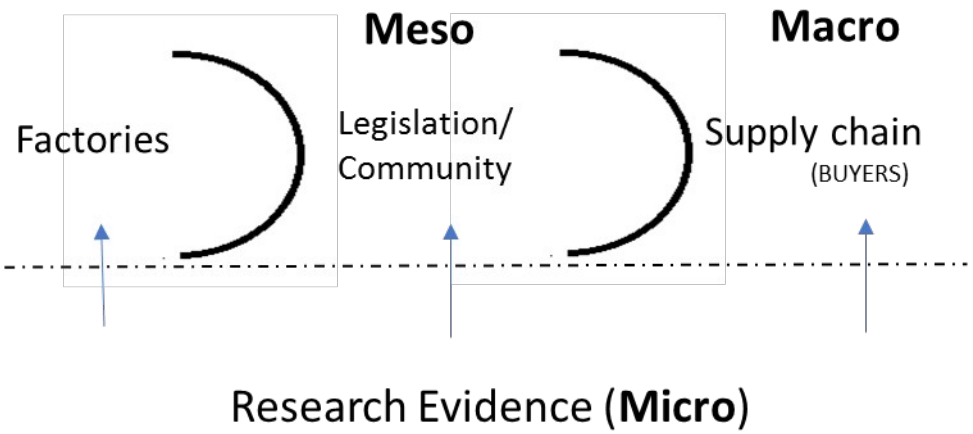
~~-~~Thirdly, if it is demonstrated that it is feasible to reduce injuries and improve safety, similar interventions could be scaled up in other factories and evidence produced could potentially contribute to informing policy development; contributing to larger-scale and longer-term occupational health improvements for this working population.

~~Lastly~~Fourthly , by focussing on the informal manufacturing sector in an urban slum context in Bangladesh and using a participatory mixed methods approach, we aim to contribute a valuable new perspective to the growing area of occupational health intervention research. This is particularly pertinent as MSF and other organisations will increasingly face such contexts as occupational injury rates are rising in countries going through rapid industrial progression,

particularly in Asia, and with current dynamics of urbanisation and industrialisation those most affected – the informal/small-scale manufacturing workforce – will continue to grow . As a result, lessons learned through this study may be transferrable to similar contexts.

Lastly, we recognise that arrangements between macro (structural and systemic), micro (research-based) and meso (institutional) level discussions in this context are inconsistent due to gaps in current legislation (notably for factories with less than 50 workers) and lack of enforcement of existing legislation. This creates conditions which may favourise conditions of poor due diligence in supply chains. Since occupational health is still a new area for the country, research has been limited and therefore there is a need for evidence to inform meso and macro levels. We aim for the study to provide leverage to influence urge the application of existing regulations and the adoption of international standards to restore dignity and safety in this marginalised population. By implementing interventions in the factories the research will aim to have immediate impact on the safety of workers; see Figure 4. Furthermore, the fact that two main national research organizations (International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b) and Centre for Injury Prevention and Research, Bangladesh (CIPRB)) both with a strong research background on injury and labour will support dialogue across meso and micro institutions.

Figure 4: Micro, macro and meso levels the research aims to influence



5. OBJECTIVES

5.1. Aim

Our overall aim is to assess the feasibility of collaborating with factory workers to design and implement public health interventions to prevent injury risks and improve work safety, therefore informing the development of a model that could be implemented more widely in this and similar neglected contexts.

Whilst varying definitions of feasibility can be interpreted in different ways, in this context we will focus on acceptability, by documenting adoption and acceptance of interventions and changes in perceptions, and practicality, by capturing resources (human resources, time, materials and cost) of implementation.

Interventions will be designed in close collaboration with participants to increase the chance of intervention to be adopted or accepted by participants.

5.2. Specific objectives

1. Understand dynamics of injury risk over time by:
    1.1. Explain ~~Describing~~ the circumstances of incidents leading to an injury (injury risks or dynamics of incident)
    1.2. Describing the circumstances of near-miss incident where no injury or illness occurs (incident risks)
    1.3. Measuring frequency and severity of injuries (burden)
    1.4. Describe ~~Understanding~~ perceptions of risks amongst owner/manager/workers

2. Design with participants acceptable interventions to reduce injury risks

3. Document intervention feasibility by:
    3.1. Describing acceptability (by in), capturing adherence to interventions and changes in risk perceptions
    3.2. Describing practicality:
        3.2.1. Documenting operational challenges and lessons learned
        3.2.2. Capturing resources (human resources, time, materials and cost) of implementation

4. Describe any changes in worker safety behaviour and incident incidence rate

6. METHODS

6.1. Study design

This intervention research will use a mixed method before-and-after design combined with a participatory approach. It will be conducted over nine months and will be supported by an industrial hygienist, whose competence will contribute to the design, implementation, and evaluation of interventions.

A **participatory approach** in this context essentially means actively involving participants (factory staff) in the research process, so in analysing injury risks, and designing and evaluating appropriate mitigation interventions. It is generally recommended when changing the way work is organized, designed and managed and has been proven to enhance implementation of various workplace interventions in other settings . Several benefits have been documented, including improved staff motivation; increased problem solving capability; enhanced buy-in and acceptance of interventions~~changes~~; and greater sustainability . This will be combined with **human-centred design** (HCD) techniques, which aim to 'meet people where they are' in order to understand the behavioural factors that govern implementation of and compliance with interventions, products or services . It is a creative and systematic approach to problem solving, grounded in the context, emotions, needs, and desires of the key stakeholders they are developing their solutions for . It has shown to enhance the use of theory-based and evidence-based approaches to intervention development, and promote behaviour change . 'Prevention by design' is also suggested to be a successful approach for other public health issues such as preventing chronic diseases, combined with evidence-based data .

Specifically, we foresee the participation of owners/workers in the following aspects of the study:

1. Analysis of risks and incidents: workers will be involved in analysing risks and incidents through pre-intervention IDIs and the collection of surveillance data (including supporting the OH surveillance worker in completing injury/incident register).
2. Collection of data: workers will be involved in collecting surveillance data as FSWs.
3. Design of interventions: participatory design FGDs will be conducted in order to co-create appropriate interventions (using the principles and methods of human-centred design such as conversation starters (questions or ideas to spark reactions on a certain theme), guided tours/ drawing or mapping of the workspace, and free-listing and ranking of intervention ideas [48].)
4. Implementation of interventions: depending on the intervention package, workers will be involved in implementation e.g. conducting training of trainers to enable workers to lead trainings for others.
5. Evaluation of interventions: interventions and the implementation process will be evaluated collaboratively with workers through post-intervention FGDs and IDIs. They will consider issues including how workers feel interventions affected occupational injuries and exposure to workplace hazards; how workers' knowledge, attitude, or

behaviours changed over time; how appropriate and acceptable interventions were; and any challenges or lessons learned in the implementation process.

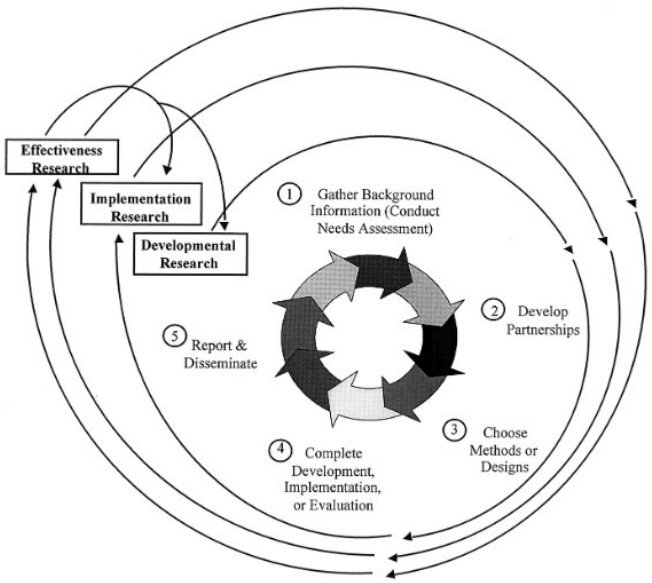
6. Dissemination and follow up of findings: findings will be shared and discussed with factory staff as part of participative sessions aiming to discuss findings and develop next steps for dissemination and follow up. It will also be an opportunity for validation and iterative data collection, documenting additional information of perceptions of the findings and participation in the study.

The before-and-after study is non-experimental design that has been validated to generate insights in the field of occupational medicine when randomised control trials are not feasible .

A **mixed methods** design has been selected as most appropriate to fulfil study objectives, allowing us to both document injury risks and understand circumstances leading to injury, and how and how they can be prevented from the perspective of the target population. Furthermore, including epidemiological, industrial hygiene and behavioural research methods is suggested to be best practice to understand critical risk factors that workplace interventions should target to improve overall work safety .

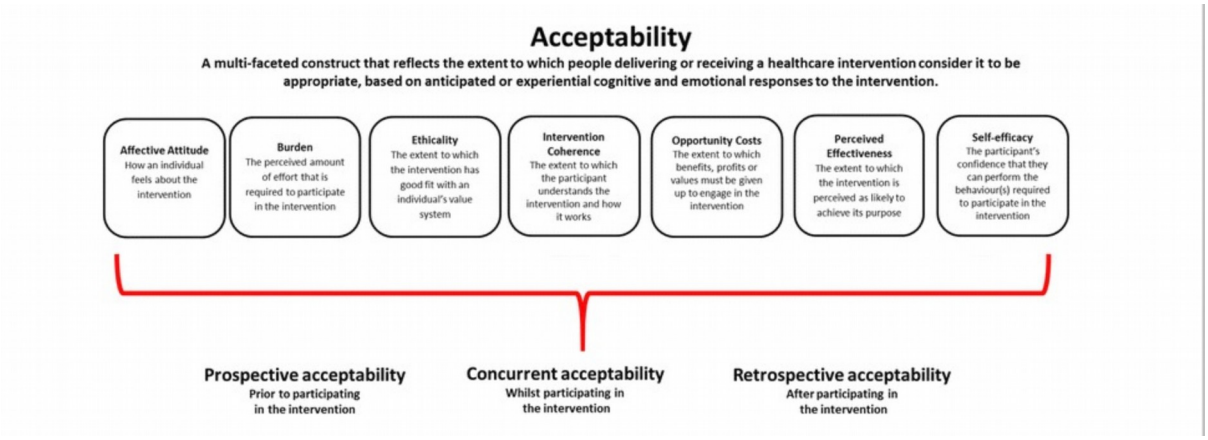
This study will incorporate elements of developmental, implementation and effectiveness research as outlined by Goldenhar et al (Figure ~~4~~5).

Figure ~~4~~5: The intervention research process: Goldenhar et al's conceptual model



Also, in further defining acceptability we draw on Sekhon et al's theoretical framework for acceptability of healthcare interventions, which comprises of seven components (figure 6). This will be incorporated into qualitative data collection tools.

Figure 6: Sekhon et al's theoretical framework for acceptability of healthcare interventions



Understanding the dynamics of injury risk has been broken down into four key components: occurrence of injury; occurrence of 'near misses'; frequency/severity of injuries; and worker perceptions of injury risk (see section 6.2). Different tools and mechanisms are proposed for improving understanding of these concepts, as outlined in Table 3 (overview of data source and indicators per objective). Existing guidance suggests that gathering and analysing information on near misses as well as accidents can provide useful information on how to prevent accidents from occurring, and therefore support the initiation of appropriate actions to promote safety in the workplace [67].

Study phases

The proposed study involves three phases (Table 2):

Phase 1 - pre-intervention (3 months): A hazard assessment referencing ~~to~~ the OSHA Hazard Assessment guidelines will be carried out to benchmark work conditions at the start of the study. Benchmarking will include objective documentation of behavioural as well as physical risks, e.g. number of repetitive movements, worker separation from moving machinery, chemical handling, etc. In-depth interviews will also be carried out with factory staff (workers, managers, and owners) to explore perceptions of risk. A surveillance system will be set up inside identified factories ~~to record~~to record and monitor incidents and related injuries, and capture dynamics of incidents occurring. Initial data will be analysed and focus group discussions will be held with factory staff to share the results and develop potential interventions. Intervention packages for each factory will be designed based on the data collected during this phase, and accompanied by Standard Operating Procedures (SOPs) to support adherence. This will also supported by literature review/desk review.

Phase 2 - intervention implementation (1-2 months): During this phase designed interventions will be set up inside the factories in collaboration with workers and managers/owners. Incident and injury surveillance will continue, and an intervention logbook will be put in place to ensure systematic documentation of interventions.

Phase 3 - post-implementation (4 months): In this phase data will continue to be collected through the surveillance system and the intervention logbook. At the end of the study a second hazard assessment will evaluate change in overall working conditions, and a second round of in-depth interviews and FGDs will be conducted to explore perceptions of risks and by in of ~~of~~ the interventions. At the close of the study all data will be analysed, as well as MSF OH clinic data (see section 6.6).

Follow -up visits will be scheduled ~~at~~ 6at 6 months and 12 months after the end of the study to assess sustainability of interventions. During the follow up visits the a third hazard assessment will be carried out to ~~agentively~~assess ~~document~~ if interventions ~~in place~~ haved been maintained along with safety conditions, and FGDs will be conducted to explore -workers' ~~prospective~~perceptions of ~~on~~ constraints and successes in terms of ~~on~~ maintaining interventions ~~in place~~.

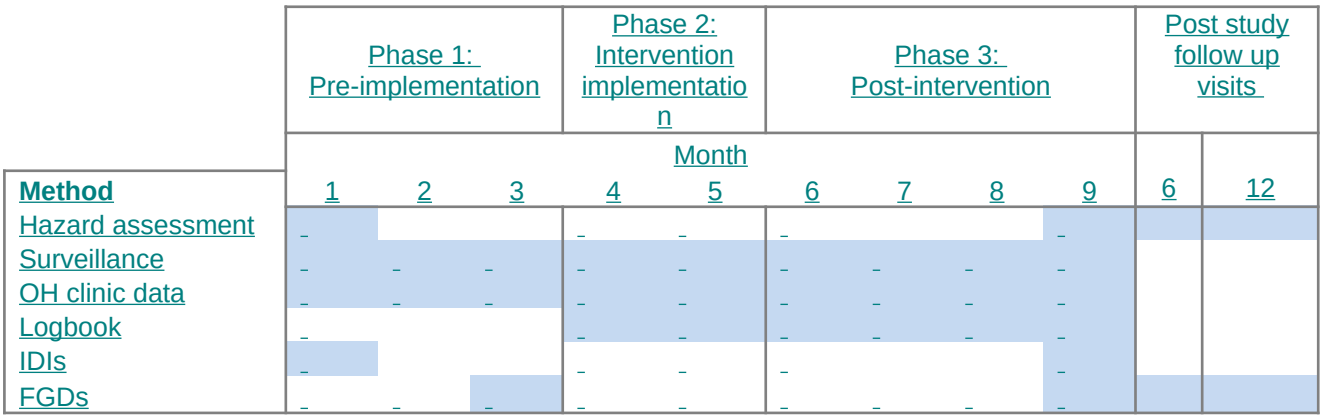
An overview of study method and timeline is provided in Figure ~~5~~7.

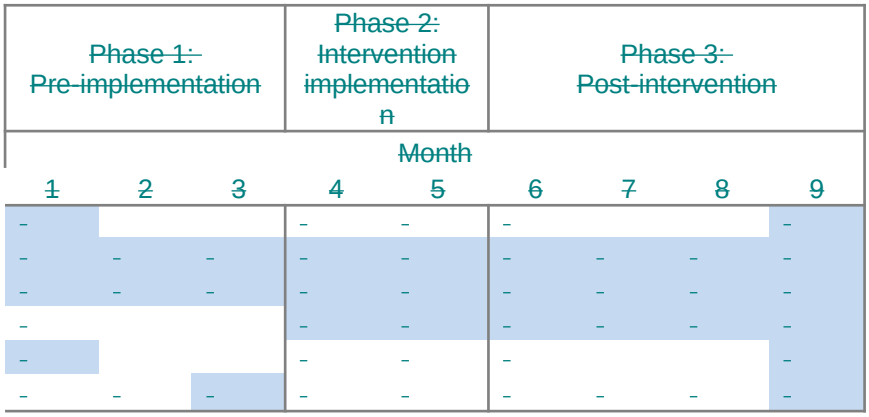
~~T~~able 2: Overview of study design

Phase	Activity	Method
Phase 1: Pre-intervention	a) Collection of pre-intervention data	1. Evaluation/ hazard assessment by industrial hygienist 2. In-depth interviews (pre-intervention) 3. Implementation of surveillance (incident/injury register) 4. Analysis of injury data from MSF OH clinics
	b) Intervention design*	5. Analysis of data 1-4 6. Participatory intervention design FGDs
Phase 2: Intervention implementation	c) Ongoing monitoring	7. Surveillance (incident / injury register) 8. Intervention 9. Intervention logbook
Phase 3: Post-intervention	d) Ongoing monitoring	10. As c)
	e) Final analysis	11. In-depth interviews (post-intervention) 12. Participatory intervention evaluation FGDs 13. Evaluation/ hazard assessment by industrial hygienist

		14. Analysis of surveillance (incident register); logbook
Follow-up post study visits		15. FGDs post-study~~)~~ 16. Repetition of hazard assessment

Figure ~~5~~7: Overview of methods over study timeframe and follow-up post study visits





Study setting and site selection

Two metal factories will be purposively selected using data from the factory hazard assessment, triangulated with injury data collected through routine MSF clinic activities. Selection will take into consideration factory size; injury rate; number of workers; turnover; and workers', managers' and owners' willingness/consent to participate. Potential study sites will be assessed and

selected prior to the commencement of the study by the industrial hygienist and the principal investigator.

Hazard assessment

The industrial hygienist will evaluate hazards ~~present~~ and relative risk on a scale of 0-5 in identified factories using a validated checklist (Annex 2). This checklist explores four areas (general physical safety, control measures, personal protective equipment and ergonomics) that reflect the performance of a factory in terms of safety. A similar ~~-~~checklist ~~This checklist~~ was used by MSF in assessing 151 factories in early 2017 (section 3.2.2), during which workers and owners of factories showed good acceptance and compliance. The checklist will also incorporate observable behaviour adopted by workers to objectively measure change in in behaviour. This will be conducted at the beginning of the study, prior to intervention development, and at the end of the study to assess changes in overall performance of safety in the workspace. A scale of 0-5t to quantify the risk was added to the previously check list used by MSF to provide an objective score to risk and inform what intervention to set up. During this assessment pictures will be taken ~~to help~~to help ~~-~~to evaluate ~~the~~ hazards observed.

In-depth interviews (IDIs)

IDIs will be conducted at the outset of the study to understand participants' perceptions of risk and injury, and post-intervention to describe acceptability of intervention package; changes in perceptions of risk; and practical issues around implementation according to package implemented.

Post-intervention IDIs will explore and evaluate participants' perceptions of intervention implementation, its impact on their perceptions of risk and injury, and highlight further suggestions for adaptation to improve future uptake (Annex 3).

Surveillance (injury / incident register)

Surveillance will be set up using incident / incident registers in selected factories, or previously validated registers will be adapted. The register will document information on incidents and injury dynamics (incidents, near-misses) occurring in each factory (Annex 4).

Focus group discussions

Following analysis of preliminary quantitative data and pre-intervention IDIs, FGDs or co-creation sessions will be conducted with workers and managers in order to discuss findings and identify potential interventions (human and technical) to mitigate injury risks.

Post-intervention FGDs will provide an opportunity for participative evaluation of the intervention and intervention process (Annex 5).

Potential interventions

Interventions will vary according to hazards and injury dynamics observed in the two factories and the input of workers, managers and owners, and will address both technical levels and human levels. Design will be based on data collected during the first phase of the study and the input of the industrial hygienist and his assistant the OH field officer. Technical interventions include those to change the organization, design or environment at work, including machines and other equipment used. Human interventions include those aiming to change human knowledge, competence, attitude, motivation or behaviours related to safety.

Possible intervention packages may include:

- Training: on use of any new equipment; standard operating procedures (SOPs); mitigation of identified work hazards (physical, chemical, biological, ergonomic); and best practice.
- Improving workspace: including layout; flow; lighting (e.g. Provide and connect Energy saving or Led lights in the factory room)
- Provision of equipment: for example, PPE
- Increase security of equipment: for example, introducing safety stops (interlocks) to machines; lids, labelling for containers containing corrosive solvents. Due to low literacy among workers labelling using pictograms will be developed
- Provision of first aid kits and training on their use
- Floor and walkway: Remove ~~the~~ obstacles from floor and walkway and place them in the sides/store room~~/ Industrial rack If available or we can provide. MSF can~~; ~~mark the walk~~-way with ~~by~~ paint ~~as well.~~.
- Engineering control: ~~MSF (log)/ hired worker will~~ cover the machine parts as identified and ~~.~~
- ~~Provide removable~~provide a removable bench for adjusting the height of machine ~~with~~to the height of workers.
- Electrical wiring~~: Hire electrician /MSF logistic to~~: ~~f~~Fix the light/ whole wiring system ~~a~~as a minimum ~~t least~~to cover up ~~this~~ cables and install new switch board.
- Replacing transformers with harmful substances to reduce health hazards.

All interventions will be discussed and adjusted with workers, owners and managers to ensure they are appropriate and adapted to the context, recognising the importance of local know-how, acceptability and experience. In addition, factory staff will be involved with the study process, intervention design and implementation to optimise engagement, ownership and sustainability, for example senior workers will be trained to lead trainings for other workers (training of trainers).

Intervention logbook

A logbook will be designed for each factory to document the practicalities of each intervention package and allow lessons learned to be drawn on the implementation process. This will include the type of intervention package, the resources planned/used (human resources, relative cost, implementation time) and any deviation from original intervention plan, including reasons and cost (Annex 6). The OH field officer will be in charge to set up and update the logbook.

MSF occupational health clinic data

As part of routine patient assessment, when a patient with an injury seeks care at an MSF clinic and injury form is completed to record severity of injury and treatment prescribed. This data will be triangulated with surveillance data on an ongoing basis throughout the study.

6.2. Definitions

Definitions used in this protocol are consistent with the International Labour Organization (ILO) and European Union (EU) adopted in occupational medicine .

Occupational incident: a work-related event(s) in which an injury or ill health (regardless of severity) or fatality occurred, or could have occurred. An accident is regarded as a particular type of incident in which an injury or illness actually occurs.

~~A n~~**Near-miss**~~:~~ ~~is~~ an incident where no injury or illness occurs. Therefore, an incident can be either an accident or a near-miss.

Incident dynamics: sequence of events that could result in an injury (e.g. stepping onto the prongs of a rake handle of rake which then swung up and hit the employee's nose).

Occupational injury: any personal injury, disease or death resulting from an occupational ~~incident~~accident; an occupational injury is therefore distinct from an occupational disease, which is a disease contracted as a result of an exposure over a period of time to risk factors arising from work activity.

Fatal injury - the most extreme outcome; where workers were fatally injured as a result of occupational incidents, and where death occurred within one year of the day of the incident~~.~~ (in our study, this will be considered to be within 9 months considering the duration of the study)

Non-fatal injury - which may be incapacitating, so that the worker is not able to carry on working, either temporarily or permanently, or is unable to carry out all the normal tasks associated with the job at the time of the incident, or may only require first aid; or: ~~or~~

Serious injuries: Injuries those requiring more than three-days' of absence from work during which the injured person is temporarily incapacitated**.**

Type of injury: describes the physical consequences for the victim e.g. bone fracture, wounds

Injury location: describes the part of the body injured

Lost workdays: days lost are generally the calendar days during which the injured worker was temporarily unable to work, excluding the day of the incident, up to a maximum of one year.

Incapacity for work: inability of the victim, due to an occupational injury, to perform the normal duties of work in the job or post occupied at the time of the occupational incident and can be *temporarily* or permanently resulting in work day loss.

Temporary incapacity: cases of occupational injury where the workers injured were unable to work from the day after the day of the incident, but were later able to perform again the normal duties of work in the job or post occupied at the time of the occupational incident causing the injury within a period of one year from the day of the incident.

Risk perception: Risk perception is based on people's judgments and evaluations of hazards they are or might be exposed to, incorporating experiences and/or beliefs embedded in contextual norms and value systems (Finucane & Holup, 2006; French et al., 2006). Within risk perception two psychological processes can be distinguished: hazard perception and risk assessment (Saari, 1976).

6.3. Study indicators

Table 3 summarising study indicators. Injury indicators are standards as used by the Occupational Safety and Health Administration (OSHA) .

Table 3: Overview of data source and indicators per objective

Objective	Indicator						
	Hazard assessment	**IDI**	**Surveillance**	**FGD**	**Intervention logbook**	**MSF OH clinic data**	
• **Understand dynamics of injury risk over time**							
1. Describe the circumstances of incidents leading to injury or near-miss			**x**			**x**	• Number of incident leading or not to an injury
2. Measure frequency and severity of injuries			**x**			**x**	• Absolute number of injury reported • Injury frequency rate (n of injuries per 100,000 workers hours) • Serious injury frequency rate (n of serious injuries: per 100,000 workers hours) • Fatal injury frequency rate (n of fatal injuries per 100,000 workers hours) • Severity (lost time hours/ per 100,000 workers hours)
3. Understanding perceptions of risks amongst factory staff		**x**		**x**			• Description of perceptions of risks per group: owner, manager, worker
• **Design interventions to reduce injury risks**	**x**	**x**	**x**	**x**		**x**	
1. Describing acceptability (adherence to interventions and changes in perceptions)	**x**	**x**	**x**	**x**	**x**		• Number of workers adhering to intervention • Description of acceptability of intervention • Description of changes in risk perception
• **Document intervention feasibility**							
1. Describing practicality (resources and process of implementation)	**x**	**x**			**x**		• Number of dedicated HR • Implementation time • Cost of training • Costs according to intervention package • Deviation from intervention package • Description of practical issues around implementation
• **Describe change in performance in work safety**	**x**						• % change in performance of work safety (general safety, control measures, PPE, and

							ergonomics)

6.4. Sampling and recruitment strategy

6.4.1 Surveillance data

Data on incidents and injuries experienced by all workers in selected factories will be captured by the surveillance system.

All workers in selected factories will be recruited during factory selection (subject to their consent; section 9.1). Should new workers join the factory the owner/manager should inform the industrial hygienist/study coordinator who will explain the study and conduct a consent process with the individual.

6.4.2 In-depth interviews

We aim to invite all factory staff to participate ~~recruit all factory staff to take part~~ in in-depth interviews, however should a larger factory be selected (over the average size of 18 workers) stratified purposeful sampling may be used to select participants who will provide the richest testimonies, and may be supported by snowball sampling should participants recommend further potential candidates to the researcher. Within this a maximum variation approach will be used to include a wide range of characteristics (for example, age, gender, duration of work in factory, incident/injury history etc.), aiming to document common themes emerging over variations.

Participants will be divided into three groups. By analysing each group separately and then triangulating the data collected from all groups we aim to draw out any notable differences between them as well as describe the communalities. Foreseen participant groups are:

a) Workers who experienced injury:
    a. during the past 3 months (for the 'before' IDIs) and
    b. during the intervention period (for the 'after' IDIs)
b) Workers who did not experience injury
    a. during the past 3 months (for the 'before' IDIs) and
    b. during the intervention period (for the 'after' IDIs)
c) Managers and factory owners, including those designated to be responsible for health and safety in the workplace

Sample size will depend on the size of the factory and the number of workers present per participant group. Ideally we aim to reach theoretical saturation for each participant group through concurrent data generation and analysis, or an iterative process, and so the final number of participants will only be known when this occurs and no new information is being generated . However, it is generally estimated to be reached after twelve to fifteen interviews . However, we recognise that this may not be possible in smaller factories (i.e. if only a few workers meet the inclusion criteria of one participant group the sample may be too small to draw any robust conclusions about that specific group) and as a result data collected from all groups may be analysed together.

Should all factory staff be included in IDIs, they will be recruited during factory selection as outlined above. Should a sample be selected, the MSF OH surveillance officer will facilitate recruitment based on existing surveillance data, in collaboration with factor owners/managers as appropriate.

Inclusion criteria:

- Factory workers injured in last 3 months (for pre-intervention IDIs) / factory workers injured during the intervention (for post-intervention IDIs) OR
- Factory workers not injured in last 3 months (for pre-intervention IDIs) / factory workers not injured during the intervention (for post-intervention IDIs) OR
- Factory owners/managers

Exclusion criteria:

- Individuals who are identified as too unwell to participate or for whom participation is inappropriate due to ongoing health issues (by themselves or an MSF team member)

6.4.3 Focus group discussions

We aim to ~~include~~ invite all workers to participate ~~all workers~~ in FGDs (again, factory size permitting).

Sample size will depend on the number of staff present in the factory, but as above we aim to reach theoretical saturation which is generally estimated to reached at between three to five FGDs .

6.5. Data collection

6.5.1 Hazard assessment

During hazard assessments photographs may be taken to be used as part of training sessions. This is mentioned explicitly in the information sheet and consent form (Annex 7 and 8). Photographs will not be used for external communication purposes.

6.5.2 Surveillance data

Data will be collected using an adapted incident/injury form (Annex 4). Within each factory, this will collect information on: ~~name,~~ age, sex, occupation, previous injury, date and time, place and incident dynamics, time shift, task at the time of the injury; injury location, type of injury, action taken immediately afterwards (first aid, back to work, to home, to hospital/MSF clinic; to emergency care; to pharmacy); lost work days.

The surveillance system will be operated by both the OH surveillance officer (an MSF nurse) and the Factory Surveillance Workers. FSWs will keep a record of the number of incidents in a dedicated tally sheet (annex 9) and inform the OH surveillance officer during his daily visits. The OH surveillance officer will investigate the incident and clinically assess the workers' injury inside the factory, so completing the incident/injury register (annex 4). The OH surveillance officer will ensure the anonymisation of incident data without using the personal details of the worker.

~~The incident/injury form will be completed by the MSF OH surveillance officer.~~

~~On a different tally shit absolute number of record number of accident, injury (Annex 9)Data will be collected by designated workers, referred to as Factory Surveillance Workers (FSWs).~~ FSWs will be selected by factory staff, and must meet minimum literacy criteria, willingness, and stable presence in the factory. FSWs will be assigned responsibility for data collection according to shifts. They will be trained on data collection (record number of accident, injury) instruments and reporting procedures, and their work will be supervised by the MSF OH surveillance officer who will visit factories daily to record ~~and check~~those data and ~~incident~~ further investigate

incident and /injury notified by the FSWs by using the incident/injury form.registers. Data will be recorded electronically using a tablet/smartphone.

6.5.3 MSF OH data

When a patient with an injury seeks care at an MSF clinic and injury form is completed to record severity (fatal/non-fatal, temporary/permanent incapacity) of injury and treatment prescribed.

6.5.4 In-depth interviews

IDIs will be conducted using flexible participatory techniques. They will take the format of a discussion and allow participants to focus on the issues they self-prioritise, although a topic guide will be used to ensure all relevant components are covered and so allow thematic comparison (Appendix 3). Themes to be explored in pre-intervention IDIs will include perceptions of working conditions, risks, and injuries, including knowledge and risk mitigation practices, incident and injury reporting and management, etc. Post-intervention IDIs will capture the same themes, as well as any changes over time and the impact of the intervention on them. Interview questions will be reviewed and refined during fieldwork in response to themes arising during the course of interviews.

IDIs will be conducted by- selected and trained members of the outreach team (supported, trained, accompanied and supervised by the qualitative methods lead)the qualitative methods lead and/or the study coordinator with the research assistant/translator, and are expected to require 30 to 45 minutes. A convenient time for interview will be arranged with workers and managers so as not to disrupt work. This will be discussed and agreed with factory owners and workers in order to ensure 'release time' or the equivalent, for participants to take part in study activities. We will not give financial compensation for participation in the study; as such we consider participation would no longer be voluntary and furthermore would set a problematic precedent for regular project activities. However, providing appropriate refreshments/snacks/meal is standard practice when interacting with workers and will be provided. IDIs will be audio-recorded and transcribed from Bangla into English by trained transcribers, with careful attention to and translation of idioms, local expressions and dialectic specificities.

Should young workers be present in selected factories (aged 8 to 17) the IDI method may be adapted to ensure language and questions are age-appropriate and to ensure young participants feel comfortable. This may include using tools such as images, factory hazard mapping (drawing maps of the factory and plotting hazards), or body mapping (drawing images of the body and plotting areas of risk/incident/injury), or asking younger participants if they prefer to be interviewed in twos or small groups or with the presence of a parent/caregiver. Details will be refined based on the presence of younger workers in selected factories, and incorporate their preferences following a consultative process; asking them what they would prefer and how they would feel most comfortable.

6.5.5 Focus group discussions

FGDs or co-creation sessions will be conducted using flexible participatory techniques and drawing on the principles of human-centred design . Intervention design FGDs will based on a topic guide that will be refined based on analysis of preliminary quantitative and IDI data. It will include methods such as conversation starters (questions or ideas to spark reactions on a certain theme), guided tours/ drawing or mapping of the workspace, and freelisting and ranking

of intervention ideas. Post-intervention design FGDs will illicit feedback on the interventions and the intervention process, and an opportunity for participative evaluation. It will consider questions such as how workers feel interventions affected occupational injuries and exposure to workplace hazards; how workers' knowledge, attitude, or behaviours changed over time; how appropriate and acceptable interventions were; and any challenges or lessons learned in the implementation process.

FGDs will be facilitated by selected and trained members of the outreach team (supported, trained, accompanied and supervised by the qualitative methods lead)~~the qualitative methods lead in collaboration with the research assistant/translators~~. FGDs will comprise of +/- eight workers, who – depending on the size and composition of the factory workforce – will be stratified to ensure participants with similar characteristics ~~will be~~are grouped together, facilitating free and open discussion (e.g. different groups may be held with men and women, and with different levels of workers, owners and managers, or clustered by age, as appropriate). Notably, dedicated groups will be held for younger workers (witout the presence of older workers) to ensure they feel comfortable to speak freely. FGDs ~~They~~ will last 60 to 90 minutes, and will be audio-recorded and transcribed as for the IDIs described above.

As above, should younger workers be present in selected factories, specific attention will be paid to ensuring FGD methods are age-appropriate, and language and tools may be modified. It is likely that smaller groups will be used (3-4 participants). Details will be refined following collaboration with young workers.

6.6. Data analysis and retentions

6.6.1 Quantitative data

All quantitative data will be entered on a tablet appositely created by the Manson Unit and a trained data clerk. The participants will be identified by a unique study specific number and/or code in any database. The name and any other identifying detail will NOT be included in any study data electronic file.

The D3/DC javascript libraries will be used to create a dashboard which will facilitate interactive visualisation of a large dataset. The dashboard will enable calculation of various standardised injury rates (incidence, frequency, severity), as well as elaborations about type of injury, part of body injured, work-related, time-related and individual variables (e.g. job task). It will automatically generate trends in indicators of interest over time and provide a map of the factory showing where injuries occur, to identify any possible hazard flow.

Indicator of interest will compute as:

I. Absolute number of injury reported
II. Absolute number of incident
III. Injury frequency rate (n of injuries per 100,000 workers hours)
IV. Serious injury frequency rate (n of serious injuries: per 100,000 workers hours)
V. Fatal injury frequency rate (n of fatal injuries per 100,000 workers hours)
VI. Severity rate (lost time hours/ per 100,000 workers hours)

Data will be analysed independently for each factory.

All the above will be easily exported for reporting. The application is entirely offline but it is possible to have remote access to visualize data.
Any paper versions of the injury form and consent forms (paper versions) and the electronic database will be stored at the MSF-OCA Headquarters in Amsterdam for a period of five years after the survey. Access to the electronic and paper documents will be restricted to the co-investigators of the study and the Medical Coordinator, and will be destroyed after five years.

VI.6.2 Qualitative data

Data will be coded inductively using NVivo. During the coding process, data will be continually reviewed and revised with emerging patterns noted and relationships between constructs identified. Emerging patterns, themes and relationships will be identified and labelled. In order to enhance reliability a subset of data will be analysed by a second researcher. In addition, certain narratives or case studies will be drawn out to ensure the individual 'stories' are not lost and to explore how the themes interrelate in particular cases.

Field notes will be taken throughout the data collection period and analysis will be ongoing. Data will be analysed using the NVivo qualitative data analysis computer software package. Analysis will be rooted in grounded theory; text data will be coded and recoded and emerging patterns, themes and relationships will be identified and labelled, allowing repeated patterns of meaning and conceptual categories to emerge from the text rather than from the mind of the researcher. Data gathered will be triangulated and negative or deviant cases analysed. A subset of the data will be analysed by a second researcher in order to enhance reliability.

As above, all electronic and paper data will be stored securely and confidentially in MSF OCA headquarters and will be destroyed after five years.

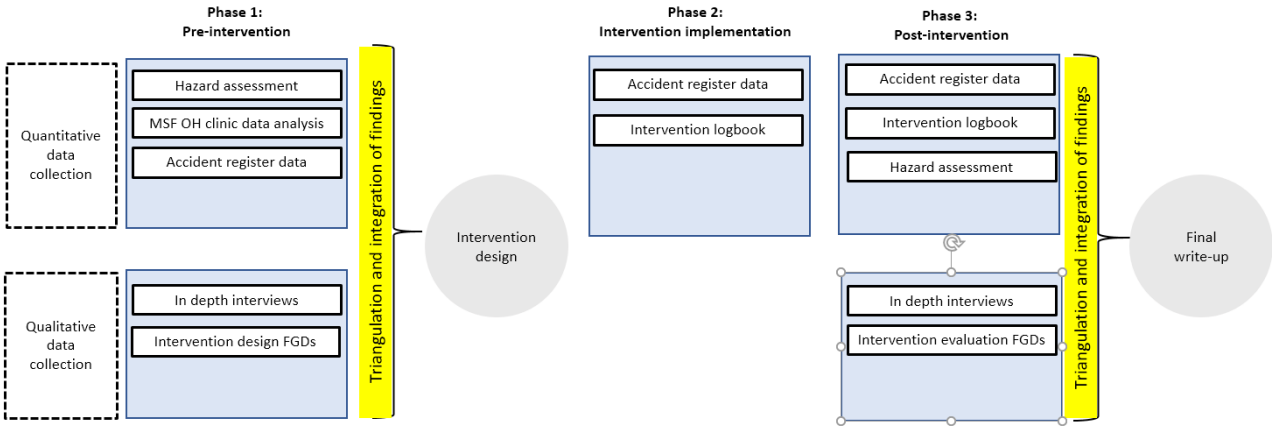
VI.6.3 Integration and triangulation of data

Data will be triangulated and integrated at various points in the study (Figure ~~6~~8), requiring close collaboration between members of the research team. Integration and triangulation of data will include the following:

- Data from hazard assessments and the incident register will inform the development of the in-depth interview topic guide.
- In-depth interviews will explore/explain results emerging from hazard assessments and the incident register and any discrepancies between risks/incidents/injuries experienced and perceived.
- Data from the OH MSF clinics will elucidate severity of injury and further identify incident posing the most risk
- Data from hazard assessments, accident register, and in-depth ~~interviews will~~interviews will inform the design of participatory design focus group discussions.
- Focus group discussions will be used to validate and explore quantitative data and co-design appropriate risk mitigation interventions.
- All qualitative and quantitative data collected during phase one will be triangulated and result in:
    a) A preliminary report documenting baseline understanding;
    b) A package of proposed interventions per factory.
- Data collected during intervention implementation (incident register and intervention logbook) may be used to modify interventions if necessary.
- Quantitative data collected during phase 2 and 3 will inform the design of in-depth interviews and focus group discussion at the end of the study period.

- In-depth interviews will explore/explain quantitative results, changes over time and any discrepancies between risks/incidents/injuries experienced and perceived.
- Final focus group discussions will be used to explore quantitative findings, and triangulate/explain intervention logbook data.
- At the end of the study all data will be analysed and triangulated and result in:
    a) A final report
    b) Other outputs as defined in the dissemination plan (section 12).
- Should any major discrepancies emerge from different data sets this will be investigated, and qualitative data collection may continue to ensure this is explained.

Figure ~~68~~: Data analysis plan



6.7. Study language

All study tools will be translated from English into Bangla and back-translated to English to ensure consistency. Group consensus on translations will be sought before implementation. All tools will be piloted prior to beginning data collection.

IDIs and FGDs will be conducted in Bangla with a translator, unless there are participants who can and want to speak English.

7. LIMITATIONS

Generalisability: As only two factories will take part in the study we acknowledge that the results will not be generalizable across Kamarangirchar, nor will they be able demonstrate the effectiveness or impact of interventions on reducing injury. However, the intention of this study is to assess the feasibility of intervening inside factories to mitigate injury risks and improve overall work safety.We aim to contribute to the development of a model for larger scale implementation and testing, leading by example through a field-adapted public health approach. In addition, in literature there is a paucity of description of interventions studies that can be used as a model in similar settings and contribute to advocacy efforts for this population.

Reliability: There is a risk that MSF's ongoing presence in the factories will influence workers' behaviours and adherence to interventions, so adherence may in part be due to this (rather than the interventions themselves). Equally, participation in the study may influence adherence, as participants are obliged to reflect on injury risks and behaviours which may have an indirect impact on perceptions of risks. The participatory approach to the study and to intervention development will in part mitigate this risk by facilitating workers' ownership of interventions and their potential benefits.

Also, whilst we would aim to interview the same workers during both the 'before' and 'after' phases of the study, we recognise that due to the turnover in workers we may find different individuals present in the factories during these phases. MSF data also indicates that workers stay on average between 1 and 5 years in each factory, so we expected this to have a minimal effect on the study (information on worker turnover will be collected and analysed along with other data). However, we also aim for intervention packages to acknowledge the issue of worker turnover and minimise its impact on interventions.

Sustainability: It is possible that it will not be feasible to maintain interventions when MSF is no longer present/implicated in the selected factories. Recognising that MSF's planned intervention is short, we are already looking for other organisations that could take the lead in the longer-term maintenance and monitoring of interventions following the study period. However, intervention packages will be designed with sustainability in mind, aiming for longer term feasibility and impact regardless of external support. Should other organisations be unable to take on longer term support, we propose follow up/monitoring by the MSF team 6 months and 12 months after the end of the study to assess sustainability. We also anticipate that the ownership of interventions engendered through their participatory development will contribute to sustainability.

Bias: It is possible that managers/owners/workers willing to participate in the study may already be predisposed to improving working conditions and as a result preventing risks will be more feasible in selected factories. However, the 2017 hazard assessment showed that all factories welcomed MSF assessment indicating a high degree of acceptance.

Desirability bias may also affect data collected; as MSF is a healthcare provider in Kamrangirchar and the organisation implementing injury risk mitigation interventions, participants may feel predisposed to report or respond in a way that is favourable to MSF or presents their factory in a positive light. This will be mitigated by ensuring a through explanation of the study and an ongoing participatory approach.

It is possible that participants may not feel comfortable to disclose injuries or speak openly about hazards, behaviours and suggestions due to concerns adverse consequences/ reprisals from factory owners/managers or co-workers. To mitigate this, clear communication and training on the objectives of the study and purpose of the injury register will be conducted; interviews will be held in a neutral and confidential space (either the participants home outside of working hours or in the MSF office); and participants for group discussions will be selected to ensure as much homogeneity as possible (i.e. not mixing workers and managers) and issues around confidentiality and anonymity will be reiterated.

8. DATA VALIDATION AND QUALITY CONTROL

8.1. Translation issues

Using translators and transcribers may influence the quality of the research findings. The translation of standard tools may also influence local interpretations, definitions and questions, and so affect the comparability of data. However, this will be minimised by thorough training and ongoing supervision of the study team; careful translation including establishing local glossaries of agreed terminology; and cross-checking of study tools and transcriptions through back-translation by another translator/transcriber.

8.2. Researcher bias

Mechanisms will be put in place to minimise the risk of the researcher's analytical bias implicit in qualitative research (for example, a sub-set of qualitative data will be coded by a second researcher; ensuring an 'audit trail' which shows the development of the methodology and analysis through field notes etc.). Reflection of the role of the researcher will also be documented through field notes and considered throughout the analysis, acknowledging the potential for bias.

The participatory design of this also study aims to minimise the risk of bias through a process of consultation and co-creation of interventions. Ongoing collaboration between (multidisciplinary) researchers and supervisors will also ensure multiple perspectives are incorporated into data collection and analysis. Practically this will include regular debriefings with the research team and a feedback session with local co-investigators and MSF team upon conclusion of data collection and prior to analysis. Peer debriefing, including oversight by an impartial researcher who will examine the data collected, final report and general methodology and provide sparring and feedback will enhance credibility and ensure validity. Furthermore, sharing the findings with participants and other stakeholder at various stages of the study creates opportunities to enhance validity by allowing participants to comment on the accuracy of the data and interpretations .

8.3. Mixed methods approach

In this study, qualitative and quantitative data will be integrated at different points during the research chronology to enhance data validity. Questions arising from ongoing quantitative analysis will be used to feed into iteration of themes explored in qualitative activities. Practically this means close collaboration between the qualitative and qualitative leads throughout the data collection period, with fixed points for interim analysis (e.g. post-testing of tools; mid-data collection). The two sets of data will then be analysed independently and the findings compiled, compared and triangulated (Section 6.6).

Triangulation will take place by searching for convergence among the different sources of information gathered to form themes or categories within the analysis, and will include collaboration between quantitative and qualitative researchers . Validation will also be established by including deviant cases and testing emerging theories, instead of only selecting examples which reiterate desirable points .

8.4. Development and pre-testing of tools

Tools have been developed based on thorough desk review, including of current standard data collection instruments, combined with the input of MSF and external stakeholders at various levels. They will be adapted based on information collected during preceding data collection (e.g. the surveillance tool will be adapted based on analysis of MSF OH clinic data and factory hazard assessment; IDI topic guides will be adapted based on preliminary surveillance and MSF OH clinic data, Figure ~~6~~8)

Tools will be pre-tested to refine methodology and ensure they are appropriate to the context. For example, the sequence of questions and response categories will be checked, and attention will be paid to the interpretation of questions; the clear and consistent translation of specific terminology and definitions; and responses during qualitative data collection are natural, and that the technique is working to capture an optimal descriptive response. Pre-testing will also assess the way the activities are perceived by participants in terms of emotional response, burden and sensitivity to the topics discussed . Any context-specific modifications will be justified and documented.

8.5. Selection, training and supervision of study team

Careful and thorough selection, training and supervision of the research team is an important element of quality control. This will ensure both technical capacity and ‘soft skills’ such as an ability to use non-judgemental language and tone; communication skills and empathy. The team will also include both male and female members to ensure participants are at ease with the research team, e.g. using female translators when interacting with female participants

~~.~~All team members will receive through training tailored to their role (including an orientation on MSF for new recruits; OH; ethics; research methods; consent process; study protocol and tools; practical exercises and role-plays on data collection; managing difficult situations; stress management etc.). The training will be given by MSF in English or Bangla, led by the principal investigator, industrial hygienist, qualitative lead, OH surveillance officer, in collaboration with other members of the study team (Table 4) as appropriate.

Pre-testing the tools will also provide an opportunity for on-the-job training and to share challenges faced and lessons learned amongst the study team, and so ensure early resolution of any concerns or discrepancies in using the research tools. Regular debriefings will be conducted during data collection to ensure a consistent approach and ongoing quality checks, to iron out any issues arising, and provide the opportunity for continued training and mentoring.

8.6. Data quality control

The study coordinator will oversee all data collected. S/he will ensure the quality of quantitative data by reviewing surveillance data and the intervention logbook on a regular basis, in collaboration with the industrial hygienist, by checking for inconsistencies in responses recorded and questions that were not completed. This will be supported by the OH surveillance officer and the project data management officer.

For the qualitative data, the qualitative methods lead will oversee the quality of data during data collection and through careful supervision of transcribers. Quality check will be built into the transcription process (e.g. a subsection of transcriptions will be double-checked by another transcriber to ensure that transcription is consistent and of a high quality). If there are inconsistencies found, then transcribers will work together to finalise the transcription. For the analysis, a sub-set of data will be re-coded by a second researcher.

Given both quantitative and qualitative teams will be involved in conducting this study, specific attention will be paid to ensuring a consistent and coherent approach, and careful integration of work and data. A ‘ways of working’ document will be developed at the outset of the study to ensure roles and responsibilities are clear, and processes are in place for information sharing. This will include provision for regular meetings, briefings and debriefings; ongoing communication and sharing of lessons; and overall supervision and quality control by the study coordinator.

9. ETHICAL ISSUES

The study will be conducted in accordance with the Council for International Organisations of Medical Sciences (CIOMS) International Ethical Guidelines for Health-related Research Involving Humans and International Ethical Guidelines for Epidemiological Studies .

The study protocol will be submitted to the Ethics Review Board of MSF. It will also be presented to the Centre for Injury Prevention and Research Bangladesh (CIPRB) to ensure the necessary resources and permissions have been obtained~~for approval.~~.

9.1. Consent

9.1.1 Consent process

After selecting factories informed consent will be sought from factory owners, managers and workers for the participation of their factory and themselves as individual workers/managers/owners.

1. Initially MSF team will meet with owners of selected factories and explain the study using an information sheet (Annex 7). The importance of voluntary consent of their staff will be explained and discussed in detail to ensure the concept and process is well understood, in order to minimise any risk of workers being put under pressure to participate.
2. If the owner agrees to the participation of their factory consent will be documented through a signed consent form (Annex 8).
3. Meetings will then be held with factory managers and workers separately to explain the study (using the information sheet; Annex 7) and ask their signed consent for participation through a consent form. The information sheet explains fully the objective of the research, that participation is voluntary and confidential. Individual information sheets will be distributed with a 'tear off' slip so that workers can volunteer to participate by returning the slip to the researchers. This will cover consent for ~~the collection of ongoing surveillance data as well as~~ participation in-depth interviews and focus group discussions. ~~(Annex 8).~~ (NB the slips with workers names will be destroyed immediately after they have been contacted and allocated an anonymous participant code; see section 91.)
4. Consent will also be asked to access patient medical data from MSF OH when completing the incident/injury register, as well as included in the general information sheet and consent form giving all workers the opportunity to participate in the study. This will clearly explain that patient/worker data will be used for the purposes of this research.
5. Explanations will emphasise that participation is voluntary and that the participant is free to withdraw from the study at any time for any reason without prejudice to future care or employment, and with no obligation to give the reason for withdrawal. In addition, specific attention will be paid to ensure that both managers/owners and workers understand that workers must participate voluntarily and should not feel any pressure to do so.
6. Consent for audio-recording will be specifically requested.
7. Consent for taking photographs during the hazard assessment will be specifically requested (although it will be confirmed that photographs where it is possible to identify individual workers will only ~~will~~ be used for hazard evaluation and internal training process and will not

be used externally for communications purposes; photographs of the workspace where it is not possible to identify individual workers may be used externally).).

8. The participant will be allowed as much time as wished to consider the information, and the opportunity to ask questions, and to decide whether they wish to participate in the study.
9. Should some workers be unable to read/write the information sheet will be explained in detail and a thumb-print will be used instead of a signature. In this instance a third party will also sign the consent form to confirm they have witnessed consent.
10. A copy of the signed Informed Consent will be given to the participant and the original signed form will be retained at the study site.
11. ~~Should any worker, manager or owner decline participation, the selected factory will not be included in the study; only factories where owners, managers and workers all give consent to participate will be included in the study.~~

In addition, consent will be requested using the same information sheets and forms prior to conducting specific data collection activities (e.g. IDIs and FGDs).

We foresee the possibility that some workers may not consent (including new workers joining the factory during the study period). The importance of voluntary participation will be emphasised throughout information and consent processed to ensure both workers and owners/managers understand its importance and do not pressure their workers/colleagues to conform.

9.1.2. Information sheets and informed consent forms

Information sheets and informed consent forms will be translated in Bangla and back translate in English for consistency. Consent forms will detail what the study will involve for the participant; the implications of participation; and the potential risks and benefits of taking part.

9.1.3 Responsibility for consent process

The consent process will be conducted by the study coordinator, with the support of the OH surveillance officer, and/or the qualitative methods lead with the support of a research assistant/translator. The study coordinator will be overall responsible for ensuring informed consent is obtained and correctly documented.

9.1.4 Consent of minors

Given a notable proportion of workers are under the age of 18, and MSF survey and clinic data suggests that younger workers are particularly vulnerable to incident and injury, it is important to include this group in the study. For workers under 18, a parent or caretaker will be required to provide written consent, in addition to the informed assent of the participant themselves. ~~.~~ Previous research experience in Kamrangirchar suggests that minors either lived with their immediate family, or if they were migrants had a family point of reference acting as a caregiver in the area (aunt, cousin etc). In this context it is possible that finding a parent/caregiver may require time; this is foreseen in study planning as part of a careful and rigorous recruitment and consent processes. In the case of illiteracy, the respondent/caretaker can consent via a fingerprint. Particular attention will be taken to ensure the process is adapted and appropriate to the age of the participant, including adapted consent/assent forms (Annex 8). ~~Should either the~~

~~caretaker/parent refuse consent or the potential participant refuse assent, s/he will not be included and the factory will be excluded from the study.~~

9.2. Confidentiality, anonymity and privacy

All individual interviews and group discussions will be held in carefully selected locations to optimise safety and privacy. These locations may vary depending on the methodology and selected factory, aiming for complete privacy. Achieving this level of privacy may be difficult in the factory setting and will require careful consideration and/or resources depending on the factory layout.

Confidentiality will be protected, and all data will be anonymised using a coding key to minimise the risk of identification of ~~to ensure it cannot be linked to a~~ specific individuals or groups of individuals. All participant data, including documents and audio recordings, ~~and~~ will be stored with an individual code. ~~All data will be stored in password protected files.~~ A master excel sheet will be kept allowing re-identification of participants and so linkage of 'before' and 'after' data. this will be password protected and kept by the study coordinator on a password-protected encrypted computer, which will be kept securely. Upon completion of the study, any identifiers will be destroyed. Recordings, notes and consent forms will be stored securely by MSF OCA for five years after which point they will be destroyed.

However, it is recognised that various aspects of this study, such as the use of a tear-off slip for participation, face-to-face interviews, and audio recording mean that participation will not be truly anonymous. Participants will be identifiable by the study team, and factory owners and workers are likely to be aware of the participation of their co-workers. However, the use of anonymous codes should minimise the risk of specific comments being linked to individual participants by anyone outside of the study team. This degree of (de)-identifiability will be carefully explained to participants during the consent process.

Whilst photographs may be taken during data collection, these will be used for hazard evaluation and internal training purposes and will not be used for external communications or in any circumstances where they may pose a risk to workers, owners or managers or breach the anonymity or confidentiality of their participation. Notably, photographs where it is possible to identify individual workers will not be shared publicly in reports, news etc. However, photographs of the workspace where it is not possible to identify individual workers may be used for this purpose.

Care will also be taken during the presentation of the research findings to ensure that the information is sufficiently aggregated so that no single individual can be identified. Specific quotes and examples will be considered and if they could lead to identification of respondents via deductive disclosure the details in the data will be modified. Content of reports will be carefully reviewed by factory staff, con-investigators and the mission team to ensure this will not put workers at risk, as preventing the identification of participating factories will not be possible. It is also noted confidentiality cannot be guaranteed in FGDs; prior to commencing participants

will be asked not to repeat anything discussed outside the group. However, all participants will be made aware that confidentiality cannot be guaranteed and this is specified in the consent forms and information sheets.

All members of the research team (including transcribers) will be thoroughly briefed on issues of confidentiality during the training and required to sign a confidentiality agreement.

9.3. Disclosure

In very exceptional circumstances confidentiality may be broken, in line with MSF protocols and best practice, should a participant disclose information that presents a serious and potentially life-threatening risk to the participant or another individual or group. For example, if a participant threatens his/her own life; a participant threatens to seriously harm another person; when child abuse suspected ; or if they reveal information posing a serious public health risk.

It is recognised that child labour can be classified as a form of child abuse, however we acknowledge this is also relatively common in Kamrangirchar and would not report such incidence to the authorities, preferring instead a three-tier approach: working with owners/mangers to ensure their workforce complies with the legal framework (e.g. no employment of children under 14; 14 – 18 year olds do not work with hazardous activities etc.); supporting individual young workers to access additional support as needed (see section 9.4); and using study findings to develop an advocacy frame for the mission related to child labour, which is currently under addressed.

Additionally, should information be revealed which present an immediate and serious risk to the life/health of workers this may inform immediate remedial action in order to prevent a serious incident during MSF's presence in the factory.

9.4. Referral

Any factory staff injured or otherwise unwell will be managed in line with the project policy, initially through MSF OH clinics and referred on should the condition be outside the scope of MSF care. Equally, should the research team encounter community members requesting assistance with health issues during the course of the study, this will be managed in line with mission procedures. Should participants become distressed during data collection due to sharing difficult experiences or working conditions they will be referred to the MSF project team for psychosocial support. The MSF medical responsible in the field will advise the study team on the referral practices for any health and psychosocial issues arising.

Should issues of abuse, exploitation, or harassment arise during the study the first point of referral will be to MSF sexual violence (SV), intimate partner violence (IPV), sexual reproductive health (SRH) and mental health services. In addition, the project has established referral pathways (including for SGBV and protection cases) as below. These pathways would also be used for study participants.

- One Stop Crises Center (OCC): Provides medico-legal assistance for victims of physical and sexual assaults.
- Bangladesh National Women Lawyers` Association (BNWLA): Provides legal support.
- Asroy: Facilitates shelter, education, adoptions for minors.

9.5. Risks

9.5.1 Risks to participants

No major risks to participants are foreseen linked to participation in the study. It is possible that reflecting on personal circumstances and difficult working conditions during interviews or FGDs could be distressing. The study team will be trained to manage such situation and the individual would be referred to the MSF clinic for psychosocial support.

It is also acknowledged that the study is potentially sensitive given that it asks workers to 'speak up' about risky working conditions, which could/they could perceive could pose risks to their employment. Whilst in other contexts engaging with workers' unions or other professional bodies may be a strategy to overcome this issue, it is notable that there are no labour unions associated with metal factories, nor that are known to function in Kamrangirchar (currently, workers' unions in Bangladesh are associated with the larger garment factories). However, this risk will be mitigated in several ways:

- Engagement with factory owners/managers: Strong engagement with factory owners since the outset of the project has ensured a positive and collaborative relationship. Thus far, owners have proved open to suggestions and improvements that result in better conditions for their workers, as demonstrated by participation in the hazard assessment and subsequent positive reception of MSF recommendations. Furthermore, protecting the interests of workers will be discussed with them in detail during initial meetings and the consent process, and the study will be framed as a collaborative exercise between MSF and all factory staff in order to improve conditions, e.g.: 'only by gaining an accurate understanding of the working environment in your factory can we design together appropriate ways to reduce them and so minimise accidents and injuries; the more risks identified, the more mitigation measures that can be put in place'. We hope this will ensure not only that workers face no adverse consequences based on their contributions to the study, but that they are actively encouraged to contribute to identifying risks in order that they be mitigated.
- Engagement with workers: As above, by exchanging with workers and ensuring they understand the objectives of the study, as well as the confidentiality and anonymity of their participation we hope to give them the confidence to participate freely without fearing adverse outcomes for their employment.
- Confidentiality and anonymity: We will maintain confidentiality and anonymity, ensuring that data are not linked to specific participants.
- Multiple data collection sources: By including multiple data collection sources and factories in the study, we aim to minimise the possibility that reporting will be linked to specific participants.

There is also risk that employers could be exposed to legal liability for contravening legal or regulatory requirements, as revealed by the study. The aim of the study is to empower owners and workers to implement good standards that fulfil legal requirements, including mandatory reporting laws. In this sense the co-investigators may play and important role in mediating and supporting owners to follow legal requirements on a case-by-case basis.

There is a very small risk that factory staff could face recriminations following dissemination of results, should they be seen unfavourably by managers/owners of selected factories or other managers/owners in the area. This risk will be mitigated by ensuring a good awareness and acceptance of the study by factory owners/managers in the area and by careful preparation of reports and other products for dissemination, in collaboration with factory staff and other stakeholders, to ensure they are appropriate and risks are minimised. Any highly sensitive or problematic results may be excluded should they pose a potential risk to individual participants, factories, or to MSF, for ~~.~~ any output intended for public dissemination will be carefully reviewed to ensure any risks, including of deductive disclosure, are minimised. Highly sensitive results may include specific details of injury incidence, abuse, or exploitation that allow the identification of any factories/owners/managers/workers, which may make them vulnerable to recriminations or hold them individually liable for infringement of regulations. Our study aims to identify such results and tackle them on a factory-per-factory basis, however in our public communication/dissemination data will be aggregated and aim to highlight these issues in general rather than singling out individuals for 'punishment'. We will also 'pilot' the dissemination of findings and ask feedback to ensure the material and presentation is acceptable; should any concerns be raised the content or presentation will be altered and the report re-piloted.

9.5.2 Risks to study team

It is possible that the study team may face injury risks or other environmental hazards during their presence in selected factories. This will be minimised by fully briefing teams on risks and risk management and ensuring necessary protective/preventative measures are in place (for example PPE).

9.5.3 Risks to MSF

No substantial risks to MSF are foreseen linked to the study; MSF's presence and work is well accepted by factory owners and managers in Kamrangirchar, and data will be collected as part of ongoing project activities.

However, it is possible that a worker could experience a severe injury during MSF's intervention, and could in some way hold MSF liable. This risk will be mitigated by establishing clear agreements with factory owners and managers, confirming that MSF is not responsible for the safety of workers, and by explaining clearly the roles and responsibilities to all factory staff. A 'hold harmless' clause will be included in the agreement with factory owners to ensure the research team will not be subject to legal action. Additionally, should any serious risks be identified posing an immediate and serious risk to the life of workers (e.g. exposed electrical

wires) remedial action may be taken as soon as possible (rather than waiting for the participatory design process), in collaboration with owners.

Equally it is possible that MSF could be implicated in an employment dispute, should an issue occur between workers and/or managers and owners linked to their participation in the study, for example if worker is dismissed and alleges this is due to information disclosed during the study. Again, this would be mitigated by stating in the agreements with factory owners/managers that MSF is in no way responsible for workers' employment, and that information disclosed must be treated as confidential and not linked to employment relationships. The participatory approach will also engender a collaborative partnership with factory staff, with whom roles and responsibilities will be discussed and agreed.

Lastly, it is possible that intensive MSF intervention in two selected factories could lead to negative perceptions or animosity from owners/workers of factories not included in the study, particularly if they request equivalent support which is not provided. This could lead to reduced access for MSF teams in non-study factories. This risk will be mitigated by ensuring all registered factory owners and managers receive a detailed explanation of the study, why certain factories were selected (inclusion and exclusion criteria), and the aim of the study to act as a catalyst for change, hoping to develop a model that can be rolled out to other factories.

With intervention /improving work environment in selected 2 factories, we could get similar demands from other factory owners to improve their factories, with possible negative implication with our regular access when we have to denied their requests.

9.5.4 Risks of stoppage of study

It is possible that for reasons beyond our control the research is stopped before data collection is finalized (security, natural disaster etc.). Safety at work could be a sensitive issue for owners and managers, and there is also a risk that this could prevent the study from being carried out or completed in the proposed location. It is also possible that a factory may dissolve during the period of the study, or management may change and new managers not accept the continued participation in the study. This will be mitigated by selecting factories with a stable presence and management structure. We also hope the good acceptance of owners/manager thus far and the positive relationship established with MSF, combined with the participatory approach of the study and ongoing dialogue will mitigate this risk.

Should premature stoppage of the study occur, we recognize this may compromise the validity of analyses and raise questions about dependability of any substantive conclusions generated from the incomplete data. Management of incomplete data will depend on the type of data already collected and the extent to which each data set is incomplete; however, to optimise input from participants we aim to utilize this data as far as possible. Available data will be analysed and presented alongside a clear explanation of the limitations arising from its incompleteness, and lessons learned will be documented.

9.6. Benefits

9.6.1 Benefits to participants

Involvement in the study will benefit participants by improving working conditions, reducing injury risks and injuries in their workplace. We also hope that by potentially increasing awareness of risk and risk mitigation, they will face less incidents and injuries in the future. The participatory nature of the study and involvement of workers to improve their working environment may also be a positive and empowering experience, which may catalyse improvements in other factories as they change workplace or engage with other workers. Lastly, by receiving training workers – particularly FSWs – will develop new skills (e.g. training, data entry etc.) which may benefit their career in the future.

9.6.2 Benefits to factory owner/managers

Factory owner/managers may benefit from enhanced employee productivity, reduced absenteeism, enhanced corporate image, improved employee recruitment and retention, increased organizational commitment and creation of a culture of health.

9.6.3 Benefits to other actor involved on supply chains

The study will be shared with other actors involved on the supply chain to be used as an example to towards achieving sustainable growth and decent employment in production for groups experiencing adverse impacts in respect of specific risks in the informal sectors.

9.6.4 Benefits to the community

It is possible that the study will generate interest in workplace safety and the feasibility of implementing interventions to mitigate injury risks. In the shorter terms, managers/owners of non-participating factories may be inspired to improve conditions in their factories, through for example learning through their peers. In this sense, the study could act as a catalyst for change in working conditions in Kamrangirchar, to the potential benefit of the working community as a whole.

9.6.5 Benefits to MSF

This study provides a unique opportunity for MSF to gain a more in-depth understanding of the mechanisms leading to injuries in registered factories as well as how to reduce them, and improve work safety and therefore an adapted programmatic approach to improving health in this population. This will ensure the existing project better meets the needs of MSF's target population, as well as inform advocacy for their improved conditions. It also allows MSF to learn about implementing participatory public health interventions, and may provide a model/approach to interventions and intervention research that is very relevant to other MSF contexts.

9.6.6 Benefits to policy and academia

The study has the potential to impact national policy for environmental health and safety and public health, should it be proved that such an approach is feasible. This may be catalysed by the collaboration of other national organisations taking on the model and piloting it more

extensively in other factories. Certain findings may also have policy or practice implications for other entities working with similar populations/in similar contexts in other countries.

In addition, this research provides the opportunity to contribute to the existing body of intervention research by focusing on the thus far under-documented rapidly industrialising urban slum context in Asia, specifically in Kamrangirchar, Bangladesh. This is particularly pertinent as urban slums and their informal working population continues to grow exponentially and the corresponding public health burden continues to grow. The study design: mixed methods before-and-after participatory intervention research, is also novel so will provide interesting insights on the feasibility and usefulness of the methodology is such contexts, thus contributing to the future intervention research agenda.

9.7. Feedback to participants, communities and other stakeholders

MSF commits to sharing study results with participants. Regular review of findings with workers will be built into the participatory nature of the study, and a summary of the final report will be shared with participants. This will be carefully developed and reviewed by co-investigators and the MSF team.

Results will be shared with other community groups and stakeholders as appropriate (Section 12).

10. COLLABORATIVE PARTNERSHIPS

10.1. Institutional collaboration

This study will be carried out by MSF-OCA in collaboration with the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b)[2] and the Centre for Injury Prevention and Research (CIPRB)[3], both based in Dhaka.

The icddr,b has strong background ~~on~~in research and policy. The CIPRB ~~,~~ is a world leading injury prevention research organi~~z~~sation in Bangladesh, leading research to measure injury burdens ~~of I injuries~~ and design intervention measures to promote safe environments. Both have strong advocacy ~~background~~components and use ~~to support~~ evidence to ~~be used in favour~~ advocate for ~~of~~ neglected populations.

Both institutions were involved in study conception and design. Initially we shared ideas during in-person meetings in Dhaka, and we then worked closely together on the development of the protocol. ~~Both organization supported the development of study protocol and procedures.~~

Representatives from these organisations will be co-investigators in the study. MSF has established relationships with these organisations and a positive track record of collaboration on previous studies.

The role of co-investigators will be to:

- ~~Support the development of study protocol and procedures~~
- Support selection of research team, as required
- Support to identify the factories where the study will be implemented
- Support to discuss with the owner and manager the aim of the study
- Support to set up surveillance procedures and training with MSF the Factory Surveillance Workers
- Review interim analyses and support intervention design
- Support training as appropriate and in line with intervention packages
- Support review of results and input into dissemination and implementation plans
- Support review of drafts of final report, and any subsequent manuscripts, abstracts, press releases and other publications arising from the study
- Support to perform follow -up visits
- Support dialogue across meso and micro institutions to increase awareness and policy on work safety in supply chain

[2] See www.icddrb.org/

[3] See www.ciprb.org/

The above collaborating institutions have also expressed an interest in continuing to follow up the selected factories after the nine-month study period, and if results demonstrate the model is feasible, potentially implementing it in other factories.

The issue of competing interests has been discussed with the field team and none have been observed.

10.2. Collaboration with factory staff

The presence of MSF in the area and its work with factory owners over the last four years has resulted in a close and fruitful collaboration with the local worker community. Continued This study aims to build on this and integrate owners, managers and workers of selected factories as partners in data collection, intervention design and evaluation.engagement with owners since the outset of the project and specific meetings with owners of selected factories during study conception and design have demonstrated consistent buy-in and commitment to improving working conditions and to collaboration with MSF. Furthermore, discussions with owners have framed the study as a collaboration, and the role of owners as key active participants in the research process. As such, tThis study aims to build on this and integrate owners, managers and workers of selected factories as partners in data collection, intervention design and evaluation.

The role of factory staff will be to:

- Factories (managers/owners) agree to the participation of the factory in the study (including allowing workers time to participate, permitting the presence of MSF staff, data collection, and intervention in their factories etc.), and to collaborate themselves with the participatory components of the study (e.g. interviews, intervention design/evaluation focus group discussions etc.)
- Factory workers: to collaborate with the participatory components of the study, including:
    - Collect surveillance data as per tools designed and following training on their use (designated Factory Surveillance Workers)
    - Participate in documentation of the situation in selected factories pre- and post-intervention (all workers or a sample should a large factory be selected, through IDIs)
    - Participate in designing and evaluating interventions (all workers or a sample should a large factory be selected, through FGDs and IDIs)
    - Review study findings and participate in the development of a dissemination and implementation plan
    - Participate in the review and evaluation of the study process
-

10.3. Role of MSF

MSF-OCA is the study sponsor and is responsible for leading the implementation of the study.

Responsibilities include, but are not limited to:

- Facilitating ongoing collaboration and engagement with collaborative partners
- Overseeing planning, preparation and implementation of the study
- Ensuring adequate resources and support for the study (financial, human resources, logistics)
- Ensuring adequate training, support and supervision of research team
- Supporting FSWs to collect surveillance data during the study period, and monitoring data quality
- Conducting data collection, analysis and report writing
- Developing a dissemination and implementation plan, in collaboration with coinvestigators and factory staff
- Disseminating and implementing results in line with plan established (including publication), with support of co-investigators and other partners

- MSF occupational clinics specifically will continue collecting data on worker morbidities to be triangulated with hazard assessment and injury register data.

11. IMPLEMENTATION OF THE STUDY

11.1. Study team

The study team is outlined in Table 4:

Table 4: Overview of study team

No.	Position	Tasks	Status	Duration
1	Principal investigator	• Support study coordinator remotely • Support coordination between different co-investigators	Current HQ staff	Part time (duration of the study, punctual support)
1	Study coordinator	• Oversee implementation of study • Responsible for quality of data collection, triangulation of data and data analysis • Prepare interim and final report	To recruit (with support of CIPRB)	Full time
1	Data management officer	• Support study coordinator with quality of data and analysis	Current project staff	Full time
1	Industrial hygienist	• Interpretation of hazard assessment • Support definition and implementation of intervention package • Contributes to final report	Current consultant	Part time (duration of the study, punctual support)
1	OH field officer	• Implement hazard assessment • Support industrial hygienist to design and implement interventions • Set up and update log book. • Coordinate training during the study	Current project staff	
1	OH surveillance officer (MSF nurse)	• Conduct daily visits to the factories • Investigate incidents (based on FSW data) • Fill Incident/ Injury register • Oversee collection of ~~surveillance data~~data on incident and injuries from the - Factory surveillance Workers • Fill the Incident/ Injury register • Referral of injured workers to MSF clinic	Current project staff	Full time
1	Factory Surveillance Workers	• Collect number of incident and injury per day and report those to OH surveillance officer	Factory workers	Full Time
1	Qualitative methods lead	• Oversees ~~and conducts~~ IDIs and FGDs	Current HQ staff	Part time (duration

		• Training, support and supervision of interviewers/facilitators (outreach team members) • Analyses data and contributes to final report		of the study, punctual support)
2	Translators/ research assistants	• Support qualitative methods lead with translation during recruitment of participants and data collection (IDIs and FGDs)	To recruit	
4	Transcribers	• Transcribe qualitative data (IDIs and FGDs) from Bangla into English	To recruit	
	TOTAL: 13			

Job profiles will be developed and study-specific positions recruited in line with mission policy.

11.2. Supervision

The study coordinator is the overall responsible for the overall implementation of the study (including logistics, training, and development of SOPs); the quality and analysis of data; and the interim and final report. She/he will implement the field part of the study together with the industrial hygienist and the OH surveillance officer. This will involve regular visits to the selected factories.

Quantitative data and report writing will be overseen by the Research Development Advisor, based in the Manson Unit, MSF UK. They also provide remote support to study coordinator and ensure good coordination among the different study co-investigators

Qualitative data collection and analysis will be overseen by the Social Science Team Lead based in the Manson Unit, MSF UK.

11.3. Training of the study team and pre-testing of tools

Training of OH surveillance officer: The OH surveillance officer will be recruited from amongst MSF staff and will have demonstrated a positive relationship and with factory staff and strong communication skills. They will undergo also two days of training on study instruments and daily visit procedures, including code of conduct and how to interact with factory workers.

Training of factory surveillance workers: Two days' training will be given to FSWs to familiarise them with the tally sheet to keep a record of the number of incidents. The OH surveillance officer will be trained to investigate incidents and fill the incident /injury register and related reporting procedures. The training will be given in Bangla by the study coordinator. It will consist of an intensive review of the tally and incident/ injury forms including role-plays. Subsequently an additional day will be dedicated to a pilot allowing for the testing of study instruments, verifying data collection skills, sharing difficulties met during data collection and

adjusting procedures accordingly~~Two days' training will be given to FSWs to familiarise them with the incident /injury register and related reporting procedures.~~

~~The training will be given in Bangla by the OH surveillance officer in collaboration with the study coordinator. It will consist of an intensive review of the incident/ injury form including role-plays. It will also involve a pilot allowing for the testing of study instruments, verifying data collection skills, sharing difficulties met during data collection and adjusting procedures accordingly.~~

Training of qualitative data collection team: One day of training for research assistants/translators will be conducted followed by a ~~one day~~one-day pilot of the topic guides and a further one day of debriefing, coaching and revision of tools if necessary (4 days in total). Training will include an introduction to MSF and MSF in Kamrangirchar; introduction to study and methods; introduction to qualitative research; ethics (confidentiality, consent, risks and benefits etc.); code of conduct; and interviewing and translating skills. It will be practical and participatory, aiming to capitalise on the knowledge and experience within the team and contribute to the appropriateness and practical planning of the data collection.

IDIs and FGDs will be held to pre-test the tools. Following the pre-test, a debriefing/review will be conducted to ensure appropriateness of tools, consistency between research assistants and address any challenges faced. Throughout the data collection tools may be refined through daily reviews of data collection, study processes, and issues emerging.

11.4. Suggested MSF support in the field

The following support to the study from MSF teams in the field is suggested:

- Support to study preparation at the field level, including presentation of the protocol to the local ethics committee and liaising with coinvestigators.
- Human resources support, such as facilitating the recruitment, contracting and remuneration of the study team as required and in line with mission policy.
- Logistics support for study preparation at the field level and during field part, such as providing communication tools and MSF ID (e. g. aprons, vests or arm bands, laptop), stationary, and printing facilities, and support for any materials as required by intervention packages designed.

11.5. Transport needed

The study will generally function within the existing car/movements allocation of the project. However, at certain time points (e.g. presentations and meetings pre- and post- study, during collection of qualitative data) an additional car from the existing fleet may be required.

11.6. Study timeframe

An indicative preliminary timeframe of the study is included below (Table 5).

Table 5: Preliminary plan of study

Phase	Activity	2017				2018												2019		
		Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar
Preparation	Protocol development																			
	Ethical review																			
	Identification of study sites																			
Phase 1: pre-intervention	Pre-intervention data collection																			
	Intervention design																			
Phase 2: Intervention	Intervention implementation																			

implementation	Ongoing monitoring																			
Phase 3: Post-intervention	Ongoing monitoring																			
	Post-intervention qualitative data collection																			
Wrap-up	Final data analysis and report preparation																			
	Dissemination of results																			

12. DISSEMINATION AND IMPLEMENTATION OF FINDINGS

Beyond the benefits of the study, the obligation to ensure results are properly interpreted and benefits are optimised and used to feed into advocacy, policy and programmes is recognised. We will develop a dissemination and implementation plan with factory staff and other stakeholders, outlining how findings will be disseminated and implemented. The exact content of this plan will depend on the study results and where/how we consider maximum impact can be achieved, but as a minimum it will include the following steps:

1. **Study participants (factory staff)**: Findings will be shared and discussed with factory staff through group meetings, using a visual presentation (booklet and/or power point). This will be done as part of participative sessions aiming to discuss findings and develop next steps for dissemination and follow up. This will include plans for contextualised advocacy, ensuring workers' wishes and voices are maintained in these activities. It will also be an opportunity for validation of findings and iterative data collection, documenting additional information of perceptions of the findings and participation in the study.
2. **Community level:** Findings may be shared with local groups of factory managers/owners through group meetings, which will provide an opportunity to explain the process and feasibility of such as interventions to mitigate injury risk.
3. **MSF project level**: Findings will be shared with MSF mission and project teams through a presentation and summary booklet (in addition to the full study report). They will be translated into practical recommendations, in collaboration with the mission/project team. This will involve identifying both practical measures to improve MSF services and occupationally health support for this population, as well as those that hat can be integrated with the project strategy, both in terms of direct adaptations to MSF activities and broader advocacy points to improve the general safety and wellbeing of this working community. These points will then be integrated into the project/mission planning during the annual planning process.
4. **National policy level:** Through collaboration with the MOHFW and sharing of findings with national level stakeholders, findings will be used advocate for improvements/changes linked with study results and to suggest policy development linked to occupational health interventions and service provision for workers. This will be done by holding meetings with relevant stakeholders to explain the findings and sharing a 'policy brief' containing a summary of relevant findings, identifying recommendations in the context of current national policy. We will ensure that the findings reach relevant users (Table 6), and that they are communicated and understood clearly through clearly produced documents/outputs, meetings and presentations, anonymised and appropriate in each of the locations per their context. This may involve presentation at national conferences, as appropriate.

Table 6: Potential organisations to target for dissemination of results

	Name	Website
Government	Ministry of Labour and Employment, Bangladesh	http://www.dol.gov.bd
	Directorate of Non Communicable Disease, Ministry of Health and Family Welfare	http://www.mohfw.gov.bd/
Non-government	Occupational Safety, Health and Environment Foundation (OSHE)	http://www.oshebd.org
	International Labour Organization (ILO) (for child labour)	http://www.ilo.org/dhaka/Areasofwork/child-labour/lang--en/index.htm
	Bangladesh Labour Welfare Foundation (BLF)	http://www.blf-bd.org
	Institution of Occupational Safety and Health (IOSH)	www.iosh.co.uk
	Alliance for Bangladesh Worker Safety (Alliance)	http://www.bangladeshworkersafety.org
	Health Without Borders	http://www.whwb.org/
	International Occupational Hygiene Association (IOHA)	http://ioha.net/
	Occupational Hygiene Training Association (OHTA)	http://www.ohlearning.com/about-ohta/purpose-and-principles.aspx
	Bangladesh Employers Federation (BEF)	http://www.bef.org.bd
University	Department of Occupational and Environmental Health (DOEH)	http://www.buhs-edu.org
Other organizations are available at http://www.oicvet.org/oshnet/imgs/news/oshnet-country-profile-bangladesh.pdf		

5. **MSF policy level:** Findings and recommendations may also be translated into the development of a model of occupational health care that could be used as a basis by MSF teams working in other similar settings in the future. They will be shared with key members of MSF OCA headquarters staff and intersectionally with other relevant personnel.

6. **International policy/academic level:** Findings and recommendations may be developed into a manuscript and submitted to a journal for publication, and may be presented at appropriate international conferences, with the aim of contributing to the global knowledge base about occupational health issues amongst small-scale factory workers in urban slums, and the improvement of service provision and response. They may also be shared with specific organisations and entities working with occupational health and urban working populations on an international level, should pertinent recommendations emerge.

   Note: Permission for publication must be obtained from MSF-OCA and the MOHFW. Study results will belong to MSF-OCA and the MOHFW of Bangladesh and authors will acknowledge that the study was funded by MSF-OCA. Authorship will be determined in

accordance with the guidelines of the International Committee of Medical Journal Editors other contributors will be acknowledged.

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