



Research for health  
in humanitarian crises

elrha

# RESEARCH METHODOLOGIES IN HUMANITARIAN CRISES



By James Smith & Karl Blanchet

## ABOUT ELRHA

We are a global charity that finds solutions to complex humanitarian problems through research and innovation. We are an established actor in the humanitarian community, working in partnership with humanitarian organisations, researchers, innovators, and the private sector.

We have supported more than 200 world-class research studies and innovation projects, championing new ideas and different approaches to evidence what works in humanitarian response. But it's not just about pinpointing what works. We transform that evidence-based knowledge into practical tools and guidance for humanitarian responders to apply in some of the most difficult situations affecting people and communities, so that those affected by crises get the right help when they need it most.

We carry out our work through two funding programmes: our research-focused R2HC programme and our innovation-focused HIF.

## RESEARCH FOR HEALTH IN HUMANITARIAN CRISES (R2HC)

R2HC aims to improve health outcomes for people affected by humanitarian crises by strengthening the evidence base for public health interventions. Our globally recognised research programme focuses on maximising the potential for public health research to bring about positive change and transform the effectiveness of humanitarian response. The work we do through the R2HC helps inform decision making.

Since 2013, we have funded more than 60 research studies across a range of public health fields.

## HUMANITARIAN INNOVATION FUND (THE HIF)

The HIF aims to improve outcomes for people affected by humanitarian crises by identifying, nurturing and sharing more effective and scalable solutions. The HIF is our globally-recognised programme leading on the development and testing of innovation in the humanitarian system. Established in 2011, it was the first of its kind: an independent, grant-making programme open to the entire humanitarian community.

Through HIF, we fund, support and manage innovation at every stage of the innovation process. Our portfolio of funded projects informs a more detailed understanding of what successful innovation looks like, and what it can achieve for the humanitarian community. This work is leading the global conversation on innovation in humanitarian response.

## OUR DONORS

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# GLOSSARY


AGSS	Adolescent Girl Safe Space
BATD	Behavioural Activation Treatment for Depression
BPHS	Basic Package of Health Services
CAR	Central African Republic
CMHW	Community Mental Health Worker
CPT	Cognitive Processing Therapy
DFID	U.K. Department for International Development
DRC	Democratic Republic of the Congo
GBV	Gender Based Violence
HHER	Humanitarian Health Evidence Review
IDP	Internally Displaced Person
LARC	Long Acting Reversible Contraceptive
OCHA	United Nations Office for the Coordination of Humanitarian Affairs
PI	Principal Investigator
PSA	Profound Stress Attunement
QI	Quality Improvement
R2HC	Research for Health in Humanitarian Crises
RCT	Randomised Controlled Trial
SMS	Short Message Service
WASH	Water, Sanitation & Hygiene




# FOREWORD

Our Research for Health in Humanitarian Crises (R2HC) programme was established in 2013 with the aim of increasing the evidence base for public health interventions in humanitarian crises. As well as funding research and working with key stakeholders to ensure research findings are used to inform policy and practice, we seek to capture broader lessons learned from conducting research in humanitarian settings. This includes documenting experience on a range of cross-cutting issues so that experience and good practice can be shared across the humanitarian health research community.

The many challenges associated with undertaking research during humanitarian crises are well understood. These include contextual challenges characterised by the specific location and type of crisis and the existence, or otherwise, of functioning health systems. There are also practical challenges associated with conducting research in such settings, including the availability of reliable pre-existing data, human resource shortages, obtaining ethics approval, access and security, logistics, and data collection, reliability and management, amongst others.



...it was time to analyse the methodologies used across a selection of studies from our portfolio, to see whether there was evidence of adaptation or innovation that could inform the work of others.



Despite the challenges of conducting research in humanitarian settings, if a sound evidence base for humanitarian public health is to be established, the same standards of methodological and statistical rigour used in other research fields need to be adopted. When the R2HC was first established it was considered that traditional impact study designs, such as RCTs, might not be feasible or even necessary to answer all research questions, and that meeting high quality research standards might require methodological adaptation and evolution to accommodate the specific practical and ethical constraints of humanitarian settings.

With more than 60 studies now funded through the R2HC, it was time to analyse the methodologies used across a selection of studies from our portfolio to see whether there was evidence of adaptation or innovation that could inform the work of others. As some of our funded research was conducted in comparatively stable protracted settings or refugee camps, and some was short-term rapid research, we decided to focus on studies conducted in challenging conflict and acute crisis settings. We anticipated we might find more methodological adaptation and innovation in such settings. A few studies not funded through the R2HC, that fulfilled the same criteria and were conducted within the same timeframe, were identified through a literature review and included.

Whilst no evidence was found of new or innovative methodologies, the reviewers found that methodology adaptation was commonplace and widespread, although not systematically documented. They call for funders, like us, to establish more rigorous requirements for researchers to document methodological changes so others can learn from the wealth of experience not currently captured in reports or journal articles. We are pleased to share the review findings and recommendations with the humanitarian health research community.


Anne Harmer




## EXECUTIVE SUMMARY

Humanitarian needs are extensive and widespread. In order to best respond to the needs of people affected by humanitarian crises, research in humanitarian settings is increasingly recognised as a valuable endeavour which allows for contextually relevant knowledge generation.

Despite widespread appreciation of the value of research conducted in humanitarian settings, the inherent dynamism and unpredictability of certain humanitarian crisis contexts, combined with a myriad of implementation challenges, have made it difficult to bridge knowledge gaps across the humanitarian sector.



From this study it is clear that adaptation of methods is commonplace, and is incorporated to ensure research can be implemented despite contextual constraints.



The launch of the Research for Health in Humanitarian Crises (R2HC) programme in 2013 represented a concerted effort to fund health research in humanitarian contexts, with 62 studies funded since 2014 through a series of annual calls for research proposals between 2013 and 2019. Since then, the operational research capacities of a number of implementing organisations have been bolstered, and dedicated research teams have prioritised research on health and other issues in humanitarian settings.

Despite a sectoral recognition of the value of research, contextual challenges have prompted donors and researchers across the sector to explore the question of methodological adaptation and innovation to accelerate the conduct of research in humanitarian settings. In a similar vein, Elrha commissioned this study to identify and analyse information related to research methods used in humanitarian settings, with a specific focus on the utilisation of adaptive or innovative approaches.

To address this question, this study combined a review of R2HC-funded studies, a peer-reviewed literature review, and key informant interviews with 39 expert researchers and implementers.

From this study it is clear that adaptation of methods is commonplace, and is incorporated to ensure research can be implemented despite contextual constraints. While adaptation is frequently described in the literature and by sectoral experts, new and innovative methods are rarely applied. Researchers continue to implement tried and tested methodological approaches, along with adaptation to sampling, randomisation, follow-up, and other core processes in pursuit of methodological rigour, ethical good practice, and reliable research outputs.

A greater focus on the adapted application of established methods, and thus an elevation of the value of implementation research, holds promise, as does the application of mixed methods research. To better understand and facilitate adaptation and the potential for innovation, space must be created to document and discuss operational challenges and changes made during the research lifecycle. Research teams should systematically incorporate justification for study methodology and document adaptive practices, while donors should consider the incorporation of core elements of the research process – including broader research capacity strengthening activities – within available funding streams.

# INTRODUCTION

In 2017, the United Nations Office for the Coordination of Humanitarian Affairs (OCHA) estimated that 141.2 million people were in need of humanitarian assistance worldwide.<sup>1</sup> More broadly, approximately 1.8 billion people are believed to live in so-called “fragile contexts”.<sup>2</sup> As of 2019, dedicated Humanitarian Response Plans were in place for 21 countries, with assistance provided to affected people in Afghanistan, Iraq, Myanmar, South Sudan, Syria, Yemen, among a number of other contexts.<sup>3</sup>

Consistently high humanitarian needs worldwide, which are often unmatched by financial and other resource commitments, have increasingly driven the pursuit of effectiveness in humanitarian action. Relatedly, the evidence base that informs humanitarian interventions has received increased attention in recent years.<sup>4</sup> The Humanitarian Health Evidence Review (HHER) conducted in 2013 identified a limited quality and quantity of evidence related to public health interventions in humanitarian settings.<sup>5</sup>

...an opportunity remains to identify and utilise research methods that are adapted for optimal implementation in humanitarian crisis contexts.

A greater awareness and appreciation of evidence-informed humanitarian programming amongst donors and implementing organisations has shaped the humanitarian research landscape in recent years. The U.K. Department for International Development (DFID) and the Wellcome Trust established the R2HC programme in 2013, with the National Institute for Health Research (NIHR) becoming an additional donor in 2018. Managed by Elrha, the R2HC is a research fund dedicated to improving health outcomes by strengthening the evidence base for health interventions in humanitarian crises. Between 2013 and 2019, 62 research projects were funded through the programme, awarded through six dedicated funding calls and three additional thematic calls with a specific focus on Food & Nutrition and Ebola research.<sup>6</sup>

Despite growing sectoral support for humanitarian research, conducting research in humanitarian settings often presents a myriad of challenges, typified by insecurity, an inability to access affected people, limited existing research infrastructure, and the limited availability of adequately trained research staff, among other issues.<sup>7</sup> These challenges pose a barrier to the conduct of rigorous research,<sup>8</sup> and yet an opportunity remains to identify and utilise research methods that are adapted for optimal implementation in humanitarian crisis contexts.

In light of the growing interest in and production of research in humanitarian settings, this study was commissioned by Elrha to identify and document the latest evidence related to the rigorous conduct of public health research in the context of humanitarian crises by examining research methods used in studies conducted since 2013. A specific focus was placed on available evidence related to adaptive or innovative methodological approaches.

<sup>1</sup>OCHA (2018), World humanitarian data and trends 2018. New York, USA: United Nations Office for the Coordination of Humanitarian Affairs

<sup>2</sup>OECD (2018), States of fragility 2018. Paris, France: Organisation of Economic Co-operation and Development

<sup>3</sup>OCHA (2019), Global humanitarian overview 2019. New York, USA: United Nations Office for the Coordination of Humanitarian Affairs

<sup>4</sup>Dijkzeul D., Hilhorst D., Walker P. (2013), Introduction: evidence-based action in humanitarian crises. Disasters. Vol. 37 (S1): S1-19

<sup>5</sup>Blanchet K., Ramesh A., Frison S., et al. (2017), Evidence on public health interventions in humanitarian crises. The Lancet. Vol. 390 (10109): 2287-2296

<sup>6</sup>Elrha (2018), R2HC research portfolio 2018. Cardiff, UK: Elrha

<sup>7</sup>Dahab, M. (2017), Operational Challenges of implementing health research in humanitarian settings. Cardiff, UK: Elrha

<sup>8</sup>Ager A., Burnham G., Checchi F., et al. (2014), Strengthening the evidence base for health programming in humanitarian crises. Science. Vol. 345 (6202): 1290-1292



# METHODOLOGY

This study was designed to identify and analyse information related to research methods used in humanitarian crises. Specific attention was paid to instances where adaptive or innovative approaches were used. The study comprised three distinct elements, including: a literature review, a review of R2HC-funded study proposals and subsequent reports, and key informant interviews. Collating data from the three different sources, the review aimed to identify methodologies frequently used in humanitarian health research between 2013–2019, and evidence and experience of innovation in research methodology where available.

## Peer-Reviewed Literature Review

Following the 2013 HHER, which documented research on public health research interventions in humanitarian settings published between 1980 and 2013, this review was conducted using a similar search strategy for the period 1 January 2013 to 7 April 2019 (search terms available on request from Elrha).

Following a preliminary review of R2HC-funded studies, research conducted with conflict-affected people in non-refugee camp settings appeared under-represented. Such contexts were also perceived to be settings in which it may be more difficult to conduct rigorous research. As such, it was anticipated that available evidence from such settings would offer the greatest insight into the need for, and application of, adaptive and innovative approaches. On the basis of this it was decided to narrow the focus of the literature review to non-camp based populations affected by conflict-related humanitarian crises.

Accounting for narrower search criteria, this literature review incorporated the HHER's health and humanitarian search terms, and included additional conflict-specific terms, and country-specific terms for contexts known to have been affected by armed conflicts between 2013–2019 (as determined by levels of conflict-related mortality and conflict-related displacement). The final list of countries included: Afghanistan, Burundi, the Central African Republic (CAR), the Democratic Republic of the Congo (DRC), Iraq, Libya, Mali, Nigeria, Palestine, Somalia, South Sudan, Sudan, Syria, Yemen.

### Inclusion Criteria

Type of study:	Primary, quantitative research
Study type:	Intervention
Populations of Interest:	Non-refugee camp based populations affected by conflict-related humanitarian crises and receiving humanitarian assistance in low and middle-income countries (based on the World Bank country classification) <sup>9</sup>
Crisis Phase:	Acute, protracted
Data type:	Must include primary data
Date of publication:	1 January 2013 – 7 April 2019
Publication languages:	English, French

<sup>9</sup>World Bank (2019), World Bank country and lending groups (online). Available from: <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups> (accessed 29th May 2019)

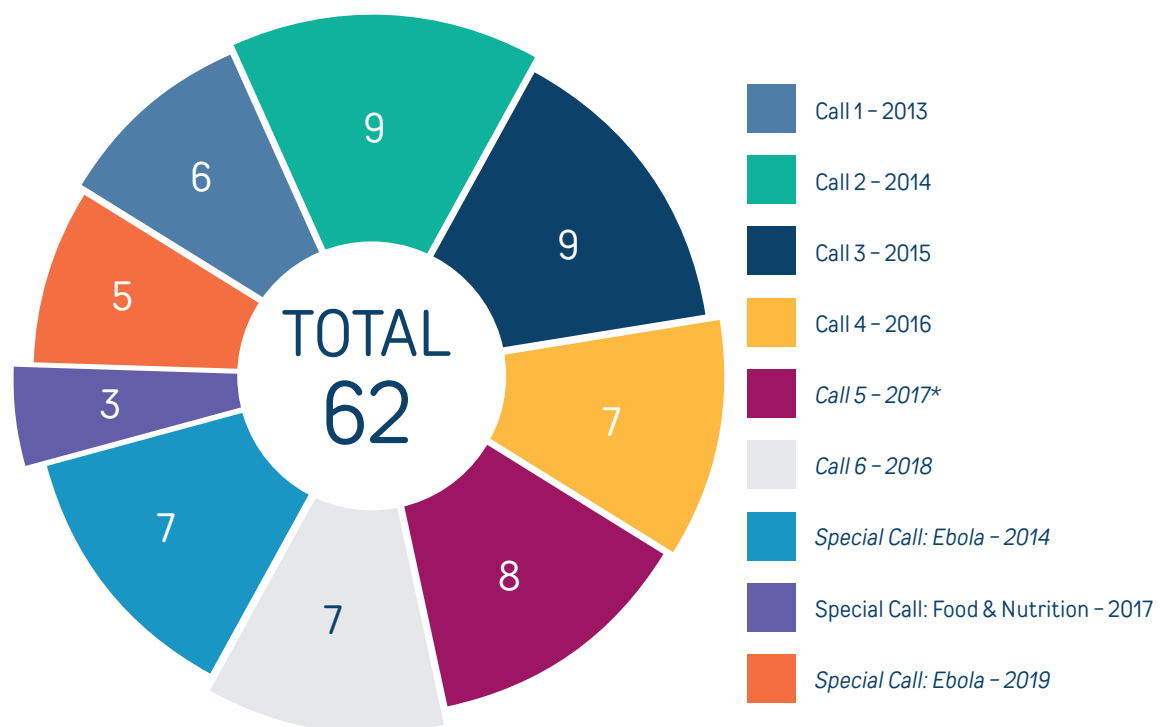
## R2HC-Funded Research Proposals & Final Reports

Access was granted to the research proposals submitted by successful R2HC applicants and subsequent narrative reports submitted later in the research process. Between 2013 and 2019, 62 studies were funded by the R2HC programme (Table 1). Studies related to research calls launched in 2017 and 2018, with grants awarded in 2018 and 2019, were not included in this review as they were either being contracted at the time of the review, or were in very early stages of implementation. Studies funded through the special calls for Ebola (2014 and 2019) were also excluded. In total, 34 proposals funded through R2HC's annual calls for proposals were reviewed.

These 34 proposals and corresponding reports follow a defined format, with a section dedicated to the justification of methodological approach and study design. In the template, applicants are specifically requested to describe:

- The chosen methodological approach and justification;
- The study design, including (where relevant) plans for baseline data collection, controls, the sampling strategy, and sample size calculations;
- Data collection and analysis methods, including key variables and means of measurement.

Table 1: Number of Elrha proposals funded by call and year 2013–2019



## Key Informant Interviews

Unstructured key informant interviews were conducted with selected R2HC-funded Principal Investigators (PIs), other key researchers identified through the professional network of the two authors, and authors of publications identified during the peer-reviewed literature review. Using a snowball approach, additional interviewees were identified on the recommendation of earlier interviewees. Interviews were conducted by Skype, telephone, or face-to-face as convenient for the interviewee. A total of 39 experts participated in the consultation process (See Annex 1 for the full list of experts interviewed). Each interviewee was asked to share their experience of conducting research in humanitarian settings, the types of methodologies they have used, the challenges they have faced, and key recommendations related to solutions required to address identified challenges

## ANALYSIS

The available R2HC-funded proposals and narrative reports were reviewed first in order to have an overview of choice of methodology among research studies conducted in recent years. A thematic matrix was developed based on narrative summaries. At this stage, key informant interviews were arranged, first with R2HC-funded PIs, followed by contacts from the authors' extended networks.

The peer-reviewed literature review was conducted alongside the key informant interviews. During this process, two additional interviewees were contacted as corresponding authors of identified studies.

Thematic analysis was conducted iteratively, with pertinent examples from the peer-reviewed literature and R2HC research portfolio used to emphasise emerging thematics.

## LITERATURE REVIEWS

### Peer-Reviewed Literature Review

630 studies were identified from three database searches (Medline, Embase and Global Health) searches (Annex 2). Following the removal of duplicates, 428 papers were subject to title and abstract review. At this stage, a further 415 papers were excluded. The most common reasons for exclusion were that papers did not describe a health intervention, reported non-primary research, or reported on research conducted by, or including members of international armed forces.

Thirteen papers were subject to full-text review, of which four were included. An additional six papers were identified during the review of references and following contact with corresponding authors, of which five provided further information related to four studies that had already been identified (i.e. reflections on best practice and implementation, additional study results and analysis). The sixth paper reported on a randomised control trial (RCT) that had been proposed as part of a larger study (captured by the database review), and which was managed as a distinct study for context-related reasons.

A total of 15 papers were selected for the final analysis, of which three had received funding from R2HC (Table 2).<sup>10,11,12</sup> These 15 papers described 10 distinct research studies of which five were conducted in the Middle East, four in sub-Saharan Africa, and one across multiple countries on two continents.

Four of the 10 studies utilised RCT methodologies, three used longitudinal methods, while the remaining three studies used one each of cohort, pre-post, and routine programme monitoring methodologies (Table 3). Detailed narrative syntheses by health thematic are presented in Annex 3. Utilisation of mixed methodologies were clearly stated in four studies.

<sup>10</sup>Dajani R., Hadfield K., van Uum S. et al. (2018), Hair cortisol concentrations in war-affected adolescents: A prospective intervention trial. *Psychoneuroendocrinology*. Vol. 89: 138-146

<sup>11</sup>Panter-Brick C., Dajani R., Eggerman M., et al. (2017), Insecurity, distress and mental health: experimental and randomized controlled trials of a psychosocial intervention for youth affected by the Syrian crisis. *The Journal of Child Psychology & Psychiatry*. Vol. 59 (5): 523-541

<sup>12</sup>Hynes M., Meehan K., Meyers J., et al. (2017), Using a quality improvement approach to improve maternal and neonatal care in North Kivu, Democratic Republic of Congo. *Reproductive Health Matters*. Vol. 25

## R2HC Proposals & Narrative Reports

The 34 R2HC-funded proposals and associated narrative reports were reviewed in full, with a particular focus on the Research Methodology section of proposals, the Methodology Update section of progress reports, and the Research Report section of final reports.

Fifteen studies were conducted across multiple contexts, followed by Africa (7), the Middle East (6), and Asia (6). Eighteen (52.9%) studies were conducted with conflict-affected populations.

RCTs were the most commonly used methodology: 13 (38.2%). Exclusively qualitative studies utilising various methods comprised eight studies, followed by seven non-RCT longitudinal studies, including quasi-experimental methodologies.

## Adaptation and Innovation in the R2HC & Literature Reviews

Of the R2HC proposals and reports and the peer-reviewed papers reviewed, innovative approaches were not explicitly stated in-text, nor clearly recognisable in the descriptions of methodology. As far as was discernable, chosen methods were well established, and appeared to be methodologically conventional means by which to address the stated research question(s).

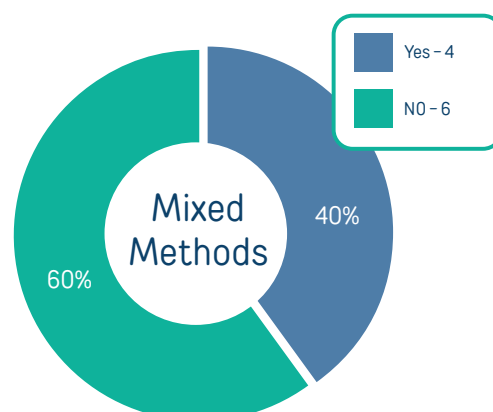
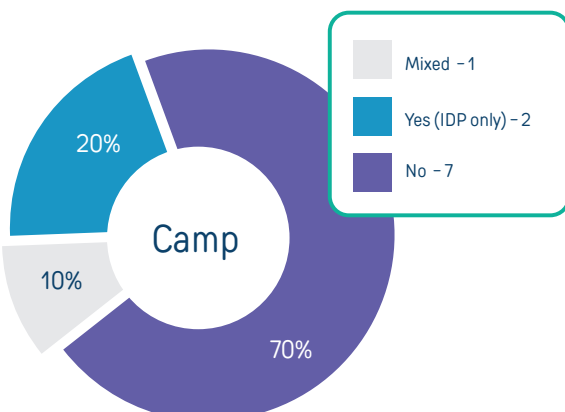
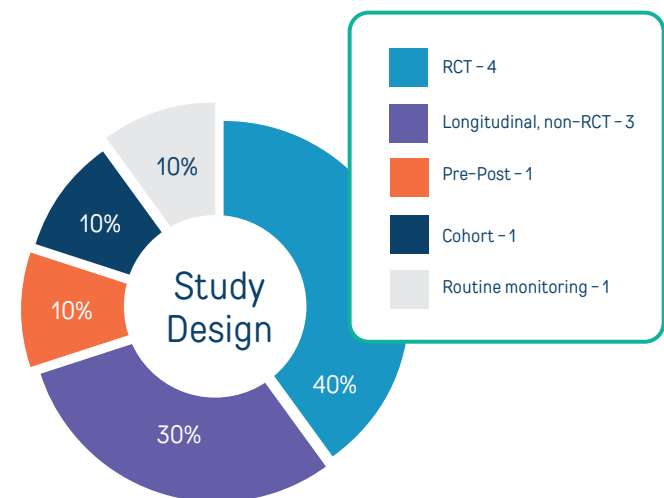
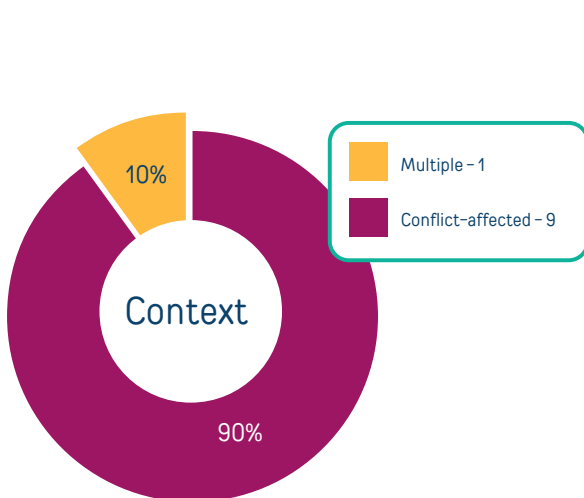
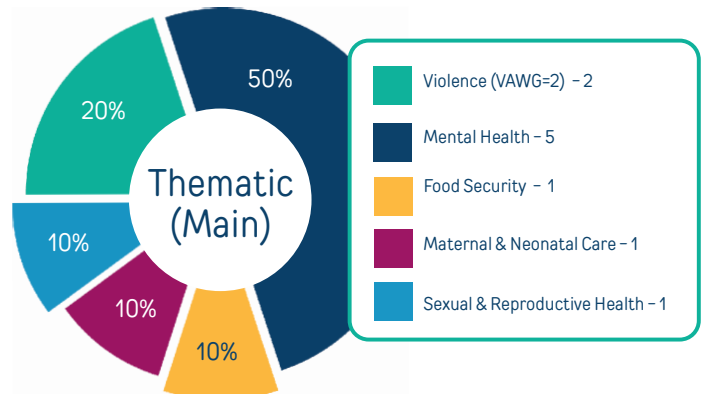
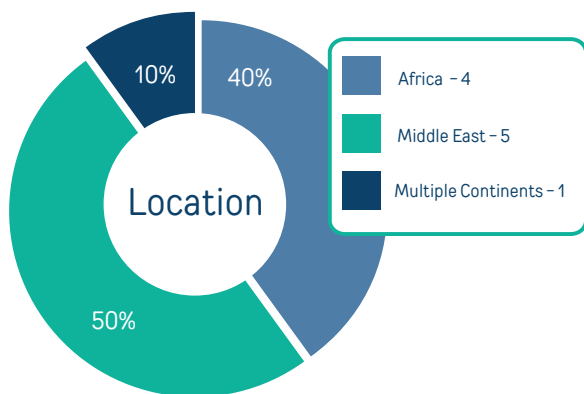
Conversely, adaptation of methods was commonplace. As anticipated, changes to methodology were infrequently cited in the final academic publications captured by the literature review. However, changes were cited in the reports submitted by R2HC grant recipients (Annex 4). The most common changes were the result of contextual constraints that required a reduced number of evaluations, fewer time-points for data collection, or the removal of a methodological component. Changes to ensure the culturally sensitive implementation of research were mentioned in two studies. Some changes related to the sample size or sampling frame, with increased sample sizes for both qualitative and quantitative components incorporated to ensure the capture of a full range of perspectives in the former, and to account for attrition in the latter. Notably, one study seeking to assess a ketamine-based anaesthetic package using a stepped-wedge approach, which would allow for comparison between included sites and sites awaiting inclusion, was altered due to health worker strikes. The intervention was implemented simultaneously across all sites, with historical data used for comparison.

Table 2: Peer-reviewed literature extraction table

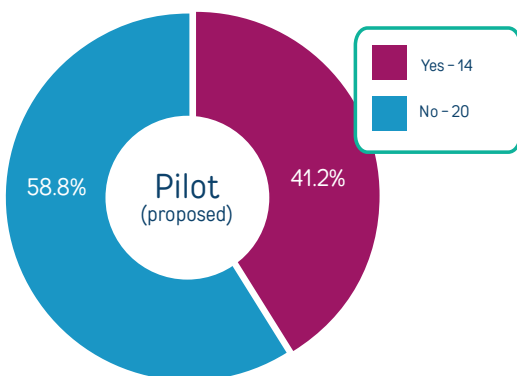
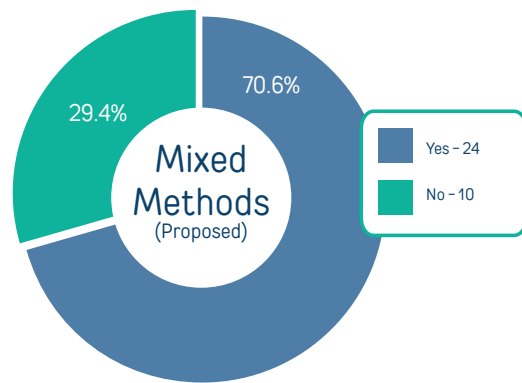
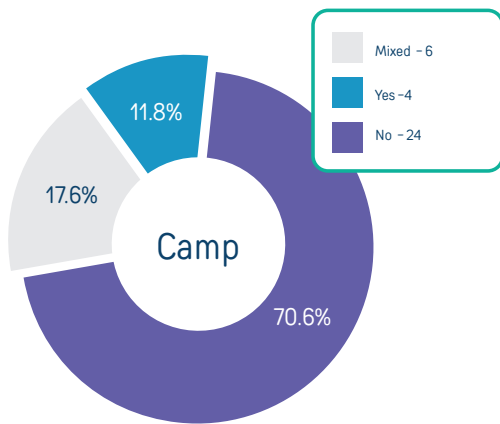
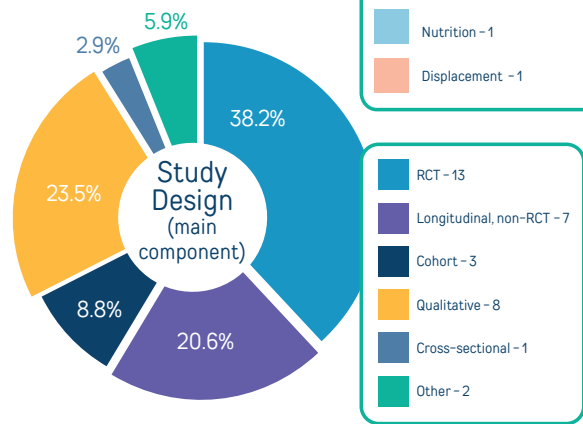
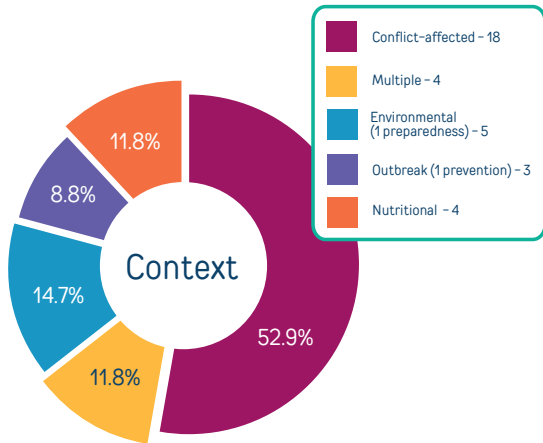
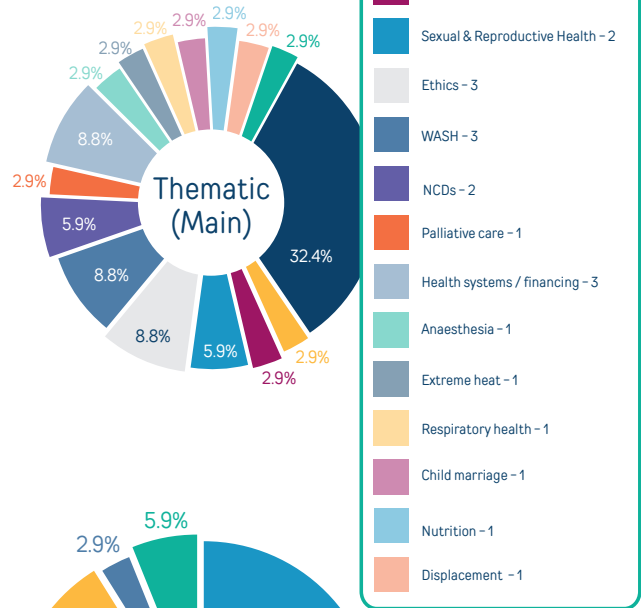
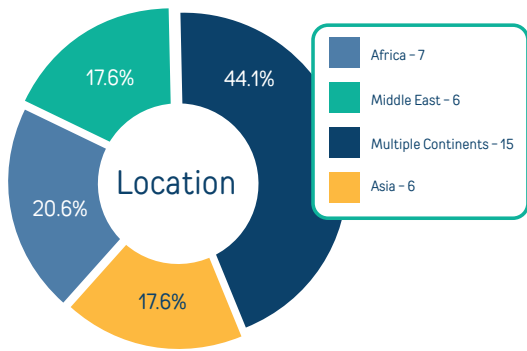
Author(s) & Date	Country	Context	Refugee Camp?	Thematic	Study Design	Local Research Partners	Mixed Methods Applied
Read-Hamilton & Marsh 2016; Glass et al. 2018; Glass et al. 2019	Somalia & South Sudan	Conflict-affected	IDP camps (Somalia)	Violence against women and girls	Longitudinal, mixed methods household	YES	YES
Bass et al. 2016	Iraq	Conflict-affected	No	Mental health / trauma	RCT	YES	NO
Bolton et al. 2014	Iraq	Conflict-affected	No	Mental health / trauma	RCT	YES	NO
Chemali et al. 2017	Lebanon	Conflict-affected (stable refugee host country)	No	Staff mental health / stress	Longitudinal mixed methods	YES	YES
Curry et al. 2015; Curry et al. 2015	Chad, Djibouti, DRC, Pakistan, Somalia	Chronic armed conflict; flooding (Pakistan)	Mixed (camps in Chad, Djibouti, DRC)	Family planning	Routine programme monitoring	NO	NO
Panter-Brick et al. 2017; Dajani et al. 2018	Jordan	Conflict-affected (stable refugee host country)	No	Mental health / stress	Quasi-experimental / RCT	YES	NO
Doocy et al. 2017	Syria	Conflict-affected	No	Food security	Separate pre-post sample household survey	NO	NO
Dozio et al. 2018	CAR	Conflict-affected	IDP camps	Mental health / trauma	Cohort	NO	NO
Falb et al. 2016; Stark et al. 2018	DRC	Conflict-affected	No	Violence against women and girls	Cluster RCT	NO	YES
Hynes et al. 2017	DRC	Conflict-affected	No	Maternal and neonatal care	Longitudinal quasi-experimental	NO	YES

Table 3:  
Descriptive summaries of R2HC  
and peer-reviewed literature reviews

Peer-Reviewed Literature Review (n=10)



### R2HC Studies (n=34)



# COMBINED THEMATIC FINDINGS

This section presents thematic findings that emerged from both the review of R2HC proposals and narrative reports, the peer-reviewed literature, and key informant interviews. An analytical framework was shaped initially by a review of the R2HC proposals and associated narrative reviews in order to establish the types of methodologies utilised and how they were justified, and the research process described (see Methodology: Analysis). The peer-reviewed literature review and key informant interviews were conducted thereafter, with thematic analysis conducted iteratively.

The thematic analysis that follows proceeds with a challenge to the notion that methodological issues present a major barrier to the conduct of research in humanitarian settings. The subsequent two sections are dedicated to the importance of aligning humanitarian response and research, and the importance of dynamism in humanitarian research. Core constituent elements of humanitarian research are outlined in Section 4, followed by an overview of some key methodological issues: generalisability, bias, and sampling. The final section challenges the pursuit of innovation in humanitarian research, and proposes a greater focus on the “basics” in humanitarian research: the importance of asking the right questions, a greater focus on the adaptation of established methods, better knowledge transfer from “stable” settings, better routine data collection, and the improved analysis of existing data.

## 1. Challenging Research or Challenging Contexts?

### 1.1. Conducting research challenged by difficult conditions

The evidence base that informs humanitarian health interventions is limited in quality and quantity.<sup>13</sup> Populations are often exposed to situations of heightened vulnerability, for which a rapid response is required. These circumstances limit the range of interventions available to practitioners, and the type of research that can be incorporated alongside humanitarian activities, particularly without prior anticipation. Exploratory research proposals may not be viewed favourably by humanitarian practitioners when research timeframes do not seem to match the urgency of immediate humanitarian response.

Where humanitarian crises extend beyond the acute phase, they are frequently characterised by: insecurity, with limited or unpredictable access to populations; limited health services often overwhelmed by health needs and stretched by a lack of health staff and equipment; and dynamically mobile populations, dispersed in urban settings, that are difficult to identify and contact. Such conditions can lead to: high levels of loss to follow up due to population mobility and general instability; difficulties sampling populations; ethical challenges associated with the randomisation of people between intervention and control groups; and challenges identifying a counterfactual or baseline data.

These contextual challenges were captured during the preparation of one R2HC-funded study conducted in Somalia, where it was not feasible for international members of the research team to enter the country due to the security situation. Such challenges were anticipated in advance, with use of mobile phones incorporated to allow for remote management and supervision and to reduce risks associated with the movement of research team members. An electronic data collection system was developed to allow for the real-time review of data and quality assurance.

“When studying the effects of an intervention, you are not working in a pristine environment. There’s more money, more NGOs. New interventions are introduced. For example, bed nets distributed when you’re looking at impregnated plastic sheeting.” (Key informant interviewee)

<sup>13</sup>Blanchet K., Ramesh A., Frison S., et al. (2017), Evidence on public health interventions in humanitarian crises. The Lancet. Vol. 390 (10109): 2287–2296



## 1.2. A multifaceted humanitarian response makes attribution of outcomes challenging

The mode of delivering standard humanitarian interventions varies between contexts, accounting for differences in local health system capacity, community sensitivities, political dynamics and the security environment, which all interact to affect the coverage and effect of an intervention. Humanitarian health interventions are also often combined with interventions from other sectors such as food security, shelter, water and sanitation, which can complicate attribution of intervention and effect.

The fidelity of health interventions (i.e. the alignment between the intervention that was planned and the intervention implemented) is regularly challenged in dynamic humanitarian contexts. However, very limited number of implementation evaluations are conducted to better understand how to optimise programme fidelity among other issues. From the peer-reviewed literature, one example of such an implementation evaluation was conducted by Curry et al.<sup>14,15</sup> The authors documented the Supporting Access to Family Planning and Post-Abortion Care in Emergencies (SAFPAC) initiative, implemented by CARE, in five crisis-affected settings (Chad, Democratic Republic of the Congo, Djibouti, Mali, and Pakistan). The researchers evaluated the implementation of each planned activity: competency-based training, facility and provider supervision, supply chain management, and community mobilisation. Data was collected at baseline and regularly monitored. However, given that the data was collected for the 'purpose of continuous quality improvement, not for the purpose of conducting systematic research in a strictly defined model', the authors acknowledged that the ability to identify causal relationships or to make generalisable conclusions is limited as the findings were from routine monitoring data rather than a randomly sampled representative group with a control.

## 1.3. Conducting research with crisis-affected populations is essential but ethically challenging

At the core of rigorous research is ethics. This is particularly the case in humanitarian contexts, where crisis-affected people may experience new and heightened vulnerabilities and trauma.<sup>16</sup> Gaining informed consent can be difficult, particularly if service provision is perceived to relate to participation in research. Practices for gaining consent must be clearly outlined, with particular attention paid to the implications of study enrolment. All studies must incorporate a clear risk-benefit analysis. While obtaining informed consent was acknowledged in the majority of peer-reviewed publications, descriptions of process and content were lacking.

Identification of control groups poses an additional issue, where denial of an intervention to one group in order to conduct a trial may be perceived as unethical, particularly where needs across the general population are high. For one R2HC-funded research group working with Syrian refugees in Jordan, a quasi-experimental approach was adopted during the first recruitment cycle, as future donor funding was not guaranteed. As such, all young people able to participate before Ramadan were included, with the remaining youth wait-listed. Only with the renewal of funding could a randomised, controlled methodology be implemented during the second cycle.<sup>17</sup>

<sup>14</sup>Curry DW., Rattan J., Nzau JJ., Giri K. (2015), Delivering high-quality family planning services in crisis-affected settings II: program implementation. *Global Health: Science & Practice*. Vol. 3 (1): 14 – 24

<sup>15</sup>Curry DW., Rattan J., Huang S., Noznesky E. (2015), Delivering high-quality family planning services in crisis-affected settings II: results. *Global Health: Science & Practice*. Vol. 3 (1): 25 – 33

<sup>16</sup>ALERT, IRESSEF, UK Nuffield Council on Bioethics, Wellcome Centre for Ethics and Humanities (2019), Joint workshop: community engagement in and for ethical research in outbreaks of infectious diseases and other humanitarian crises. Workshop Report. Dakar, Senegal

<sup>17</sup>Panther-Brick C., Dajani R., Eggerman M., et al. (2017), Insecurity, distress and mental health: experimental and randomized controlled trials of a psychosocial intervention for youth affected by the Syrian crisis. *The Journal of Child Psychology & Psychiatry*. Vol. 59 (5): 523–541

## 2. Aligning Humanitarian Response and Research

### 2.1. Choice of research strategy must be informed by the local context

In situations where researchers work with humanitarian practitioners to design and conduct research, practitioners should be involved during all stages of study development and implementation. Research institutions rarely have the same local capacity as humanitarian organisations in terms of staffing, logistics (e.g. security monitoring, transportation, field communications) and local networks. When security conditions deteriorate, researchers are often the first to face movement restrictions as “non-essential” staff. Several researchers attest that, in such contexts, practitioners who are still able to travel are often trained in data collection and supervision, and act as proxy researchers. Such role and responsibility adaptations are not exceptional but are infrequently documented by researchers.

#### Case Study 1: Use of electronic tools for data collection / management

If suitable in relation to the chosen research question, researchers increasingly use electronic tools such as tablets and phones to facilitate data collection. Such technologies enable research teams to limit the movement of researchers at the local level, while maximising data management. The individual responsible for data collection may be a local health professional who incorporates data collection alongside their other obligations. Such management choices require rigorous data quality monitoring and feedback coupled with regular communication between study coordinators and those individuals responsible for data collection at the local level. Additional efforts must be taken to ensure that local staff are not placed under undue risk, or that research-related obligations interfere with service delivery.

iPads were used by trained local research assistants during the evaluation of UNICEF’s Communities Care: Transforming Lives and Preventing Violence programme in Somalia and South Sudan.\* Use of electronic data collection methods reduced the logistical burden of paper-based data collection, and allowed for real-time data management.

*\* Glass N., Perrin A., Clough P., et al. (2018), Evaluating the communities care program: best practice for rigorous research to evaluate gender based violence prevention and response programs in humanitarian settings. Conflict & Health. 12:5*

## 2.2. Research is distinct from implementation

The implementation of humanitarian programmes is not the role of researchers. Research institutions rarely have the capacity to manage the implementation of an intervention and simultaneously conduct research, as might be the case when an RCT is conducted in a non-humanitarian setting. There must be a clear separation between implementation and research roles both for ethical and practical reasons.

This poses a number of constraints for both parties: researchers may wish, for example, to randomise participants during progressive programme implementation, while practitioners may wish to roll out interventions based on feasibility and convenience. The time constraints facing both parties also differ; practitioners are often required to act as quickly as possible, while researchers need to consider other processes including adherence to research ethics frameworks and more.

The distinction between humanitarian service provision and research was problematised by one key informant interviewee, who recognised the way in which participant engagement with research may be skewed where particular participants responses are perceived to be linked to access to additional services or support, which in turn raises ethical issues pertaining to informed consent and voluntary participation.

All but two studies identified in the peer-reviewed literature described research conducted in collaboration between researchers and non-governmental organisations (NGOs)<sup>18,19,20,21,22,23,24, 25,26,27,28</sup> and in the case of one study, a collaboration between researchers and a governmental ministry.<sup>29</sup> The remaining two studies were conducted entirely by representatives of two non-governmental organisations. Such collaborative research partnerships allow for a clearer division of role and responsibilities between implementing organisations and research partners. As explained by two key informant interviewees, it is essential that researchers orientate their studies based on the priorities of both humanitarian practitioners and crisis-affected populations. Reflecting this, it is a requirement that all research funded through the R2HC programme is jointly implemented by academic groups in collaboration with at least one humanitarian partner.

<sup>18</sup>Dajani R., Hadfield K., van Uum S. et al. (2018), Hair cortisol concentrations in war-affected adolescents: A prospective intervention trial. *Psychoneuroendocrinology*. Vol. 89: 138-146

<sup>19</sup>Panter-Brick C., Dajani R., Eggerman M., et al. (2017), Insecurity, distress and mental health: experimental and randomized controlled trials of a psychosocial intervention for youth affected by the Syrian crisis. *The Journal of Child Psychology & Psychiatry*. Vol. 59 (5): 523-541

<sup>20</sup>Bass J., Murray SA., Mohammed TA., et al. (2016), A Randomized Controlled Trial of a trauma-informed support, skills, and psychoeducation intervention for survivors of torture and related trauma in Kurdistan, Northern Iraq. *Global Health: Science & Practice*. Vol. 4 (3): 452-466

<sup>21</sup>Bolton P., Bass JK., Zangalla GAS., et al. (2014), A randomized controlled trial of mental health interventions for survivors of systematic violence in Kurdistan, Northern Iraq. *BMC Psychiatry*. 14: 360

<sup>22</sup>Doocy S., Tappis H., Lyles E., et al. (2017), Emergency food assistance in northern Syria: an evaluation of transfer programs in Idleb Governorate. *Food and Nutrition Bulletin*. Vol. 38 (2): 240 - 259

<sup>23</sup>Falb KL., Tanner S., Ward L., et al. (2016), Creating opportunities through mentorship, parental involvement, and safe spaces (COMPASS) program: multi-country study protocol to protect girls from violence in humanitarian settings. *BMC Public Health*. 16: 321

<sup>24</sup>Stark L., Seff I., Asghar K., et al. (2018) Building caregivers' emotional, parental and social support skills to prevent violence against adolescent girls: findings from a cluster randomised controlled trial in Democratic Republic of Congo. *BMJ Global Health*. 3: e000824

<sup>25</sup>Read-Hamilton S., Marsh M. (2016), The Communities Care programme: changing social norms to end violence against women and girls in conflict-affected communities. *Gender & Development*. Vol. 24 (2): 261-276

<sup>26</sup>Glass N., Perrin A., Clough P., et al. (2018), Evaluating the communities care program: best practice for rigorous research to evaluate gender based violence prevention and response programs in humanitarian settings. *Conflict & Health*. 12:5

<sup>27</sup>Glass N., Perrin N., Marsh M., et al. (2019), Effectiveness of the Communities Care programme on change in social norms associated with gender-based violence (GBV) with residents in intervention compared with control districts in Mogadishu, Somalia. *BMJ Open*. 9:e023819

<sup>28</sup>Hynes M., Meehan K., Meyers J., et al. (2017), Using a quality improvement approach to improve maternal and neonatal care in North Kivu, Democratic Republic of Congo. *Reproductive Health Matters*. Vol. 25

<sup>29</sup>Chemali Z., Borba CPC., Johnson K., et al., (2017), Humanitarian space and well-being: effectiveness of training on a psychosocial intervention for host community-refugee interaction. *Medicine, Conflict & Survival*. Vol. 33 (2): 141-161

## 3. Humanitarian Research must be Dynamic

### 3.1 Changes to methods and process are commonplace

Changes to methods and the broader research process during the course of a study may be necessary due to a variety of factors, many of which are mentioned in the R2HC grant proposals and reports: restriction of the movement of international or national personnel due to security issues; large scale population movements or a rapid increase in humanitarian needs; restrictions placed on the supply of core commodities; and more. Conducting research in such dynamic contexts can affect the study sample size, choice of study group, choice of data collection tools (from face-to-face to telephone interview or electronic survey), data sources (from primary to secondary), the ability to follow cohorts over time, and ultimately the ability to continue a research project.



*“The sector must be more willing to engage with imperfect research”* (Key informant interviewee)



As with other donors, “significant” protocol changes must be notified to Elrha for review and are usually escalated to R2HC Funding Committee members for approval. However, there is presently no clear definition of “significant” and as such the decision to notify Elrha is determined by the research team. Interpretation of “significant” is likely to vary between research teams, particularly when challenges, barriers and corresponding adaptation appear “routine” in difficult humanitarian contexts.

For one R2HC-funded study conducted in Lebanon, the research team had to make changes to the methodology, with additional data collection and sample size changes introduced as study participants either started or stopped receiving multi-purpose cash-based transfers. Coordination and planning with the humanitarian organisation dispensing the cash-based transfers minimised the impact of these changes.

From the peer-reviewed literature, a proposed four-arm randomised control trial in Kurdistan became two distinct studies after the research team identified population-based differences in religiosity, political conservativeness, and trauma exposure between the proposed study sites. One study evaluated the impact of a supportive counselling programme in Dohuk governorate,<sup>30</sup> while a second study evaluated two psychotherapeutic interventions, Behavioural Activation Treatment for Depression (BATD) and Cognitive Processing Therapy (CPT), in Erbil and Sulamaniyah governorates.<sup>31</sup> Two study sites in Somalia were removed during the analysis of data related to UNICEF’s Communities Care: Transforming Lives and Preventing Violence programme, due to insecurity in an intervention district, and the influx of IDPs, an increase in GBV cases, and engagement of other humanitarian actors in a control district.<sup>32</sup>

<sup>30</sup>Bass J., Murray SA., Mohammed TA., et al. (2016), A Randomized Controlled Trial of a trauma-informed support, skills, and psychoeducation intervention for survivors of torture and related trauma in Kurdistan, Northern Iraq. *Global Health: Science & Practice*. Vol. 4 (3): 452-466

<sup>31</sup>Bolton P., Bass JK., Zangalla GAS., et al. (2014), A randomized controlled trial of mental health interventions for survivors of systematic violence in Kurdistan, Northern Iraq. *BMC Psychiatry*. 14: 360

<sup>32</sup>Glass N, Perrin N, Marsh M, et al. (2019), Effectiveness of the Communities Care programme on change in social norms associated with gender-based violence (GBV) with residents in intervention compared with control districts in Mogadishu, Somalia. *BMJ Open*. 9:e023819

## 3.2. Research modification and challenges are inconsistently documented

While adaptation to research studies may occur frequently, such changes are inconsistently documented. While the R2HC reporting templates require teams to document challenges they have experienced during the research process, some of these challenges are reported in a superficial manner.

This reporting bias may be explained by the fact that researchers are obliged to report to the donor and may downplay difficulties experienced during the implementation phase. Beyond donor reporting mechanisms, such challenges rarely appear in publicly available peer-reviewed publications. As a result, a great deal of useful implementation knowledge and experience is not captured and shared with the wider humanitarian sector.

# 4. Core Elements of Humanitarian Research

## 4.1. Mixed methods increasingly the norm

A number of key informant interviewees felt that “robust” research is still frequently understood as synonymous with quantitative research, and “gold standard” methodologies such as the RCT. A perceived propensity towards positivist methodologies among funders and review committees has further entrenched this mentality.<sup>33</sup>

However, where the collection of quantitative data is difficult due to contextual constraints (e.g. a lack of baseline data, difficulties verifying the credibility of information), qualitative methods were recognised by one interviewee as an adaptive response to quantitative data quality issues, with mixed methodologies widely appreciated as beneficial, as long as they are clearly required in order to address the stated research question and perceived knowledge gaps. Another interviewee reiterated that choice of methodology must be shaped by the type of question researchers seek to answer; given that many challenges are socially grounded insofar as they pertain to human behaviour, qualitative methods as yet have untapped potential. However, the same interviewee observed that the quality of qualitative research proposals and research outputs has yet to reach a sufficiently high standard.

Mixed methods combine multiple methodologies, including both qualitative and quantitative research methods. Such research engages multiple concepts, tools and methods to answer a research question. Mixed methods also allow for data to be collected in different ways from multiple data sources, allowing for the triangulation of data and increased confidence in research findings. Four unique studies identified from the peer-reviewed literature employed mixed methodologies.<sup>34,35,36,37,38,39,40</sup> Twenty-four (70.6%) of the R2HC studies clearly described a mixed methods approach. For example, one R2HC-funded study identified the social status of interviewees during interviews, which was then cross-checked with data compiled by UNHCR.

<sup>33</sup>Blanchet K, Allen C, Breckon J, Davies P, Duclos D, Jansen J, Mthiyane H, Clarke M. (2018) Using Research Evidence in the Humanitarian Sector: A practice guide. London, UK: Evidence Aid, London School of Hygiene and Tropical Medicine and Nesta (Alliance for Useful Evidence)

<sup>34</sup>Read-Hamilton S., Marsh M. (2016), The Communities Care programme: changing social norms to end violence against women and girls in conflict-affected communities. *Gender & Development*. Vol. 24 (2): 261-276

<sup>35</sup>Glass N., Perrin A., Clough P., et al. (2018), Evaluating the Communities Care program: best practice for rigorous research to evaluate gender based violence prevention and response programs in humanitarian settings. *Conflict & Health*. 12:5

<sup>36</sup>Glass N., Perrin N., Marsh M., et al. (2019), Effectiveness of the Communities Care programme on change in social norms associated with gender-based violence (GBV) with residents in intervention compared with control districts in Mogadishu, Somalia. *BMJ Open*. 9:e023819

<sup>37</sup>Chemali Z., Borba CPC., Johnson K., et al., (2017), Humanitarian space and well-being: effectiveness of training on a psychosocial intervention for host community-refugee interaction. *Medicine, Conflict & Survival*. Vol. 33 (2): 141-161

<sup>38</sup>Falb KL., Tanner S., Ward L., et al. (2016), Creating opportunities through mentorship, parental involvement, and safe spaces (COMPASS) program: multi-country study protocol to protect girls from violence in humanitarian settings. *BMC Public Health*. 16: 321

<sup>39</sup>Stark L., Seff I., Asghar K., et al. (2018) Building caregivers' emotional, parental and social support skills to prevent violence against adolescent girls: findings from a cluster randomised controlled trial in Democratic Republic of Congo. *BMJ Global Health*. 3: e000824

<sup>40</sup>Hynes M., Meehan K., Meyers J., et al. (2017), Using a quality improvement approach to improve maternal and neonatal care in North Kivu, Democratic Republic of Congo. *Reproductive Health Matters*. Vol. 25

## Case Study 2: Step-wise incorporation of mixed methods – key informant interviews and an RCT

An R2HC-funded study sequentially incorporated mixed methods as recommended by the UK Medical Research Council's Framework for the Development of Complex Interventions.\* The study was structured in five phases: (1) key informant interviews to ensure cultural appropriateness, (2) a pilot RCT, (3) a process evaluation; (4) a full-scale RCT, and (5) an additional process evaluation.

In the first phase, the research team conducted community consultations with the goal of optimising engagement, understanding local perspectives, and to inform the cultural adaption of the content and approach. In the second phase, the research team conducted a pilot – “feasibility” – RCT that helped to inform the research team of the feasibility, safety and optimised delivery of the intervention, and identify factors that may need to be addressed prior to roll-out of the full RCT. This phase was critical in the identification of procedures pertaining to: selection, training, and supervision of personnel; randomisation, and blinding of evaluators; clarity of measures; and recruitment and retention. In the third and fifth phases, a process evaluation was carried out to assess the factors that promoted and impeded participation in, and response to, the trials.

For such a step-wise approach to have added value, time is needed to ensure that issues can be addressed as they arise; two years was perceived as a tight timeframe for such a comprehensive, multi-stage research study.

\* MRC (2019), *Developing and evaluating complex interventions. The U.K. Medical Research Council: London*

Mixed methods are increasingly utilised in research conducted in humanitarian settings. However, a mixed methods approach does not simply relate to the combination of different methods. Both results and analysis must be viewed together, and analysed in a sophisticated manner, which in turn requires specific research skills and experience. Despite the growth in application of mixed methods, some data sources are still considered under-utilised. One interviewee observed that large, alternative data sources such as social media are yet to be fully harnessed, particularly in the absence of validated tools to assist in data extraction and analysis.

## 4.2. Local researchers and partnerships: an essential asset

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• “There is always that one thing that comes up that you didn’t think  
• to ask. If I wasn’t there ... talking with the various staff we were  
• working with ... it would have been harder to make those plans,  
• change how we were doing things.” (Key informant interviewee)

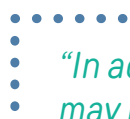
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Five of the 10 unique research studies identified in the peer-reviewed literature search made clear reference to the engagement of local partners, with varying degrees of participation in the research process. International researchers often work closely with local researchers for a variety of reasons, including to improve contextual insight, support and learn from local researchers, facilitate access, and strengthen local capacities. Such work generally involves working closely with local researchers from data collection through to the publication of study findings. Building a trusting relationship with local researchers is perceived as central to the pursuit of high quality research. Trust is often combined with regular and transparent communication between the two parties, which enables researchers to share information in order that appropriate decisions can be made in a timely manner.

When it is not possible for certain researchers to visit a local site for security or other reasons, research has on occasion been adapted so that researchers from, or with better access to, affected areas are able to conduct data collection with remote support provided by international colleagues. In one case, a research partner was unable to leave Goma due to security concerns. A strong research team was put in place by the implementing partner organisation, while training (including training of trainers) was conducted in Goma. Teams were then able to train colleagues in more remote locations on how to conduct exit interviews. While remote supervision had the potential to pose data quality issues, particularly in the absence of electronic tools for data collection and real-time data quality monitoring, the added value of data from direct observation and facility exit interviews warranted the additional investment.

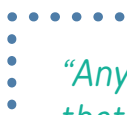
Supplementary interviews may be conducted by international researchers by phone, Skype or another secure platform. Such was the case with one R2HC-funded research group studying ethical issues faced by health practitioners working in Syria. Almost all of the key informant interviews were conducted remotely. Given the sensitive nature of such interviews, a more secure system than Skype was required by the institution's ethics review board.



*“In achieving access, locals can get nearly everywhere. Researchers may need to move towards use of private organisations and consultancies where there is a local connection. There is a reliance on local populations. This may affect the quality depending on how well trained people are, and how well monitoring and supervision is put in place.”* (Key informant interviewee)



One interviewee observed that where local researchers co-own the research process, the hierarchy between researcher and study participant is diminished, replaced by a culture of ownership and participant agency. Reinforcing participant agency allows for a productive interaction in which researchers and participants engage in problem-solving together. It is with such local, non-hierarchical interaction that new ways of thinking and acting can emerge.



*“Any research should include as co-PI local academics and researchers ... that removes a lot of problems straight away.”* (Key informant interviewee)



Where local researchers are involved in the research process, potential study participants may be less distrustful and suspicious of research activities. One key informant described a proposed methodology that had the potential to raise suspicion among a conflict-affected population, so much so that the international NGO involved in the research project was reluctant to proceed. With the support of a researcher with links to the local population, members of the community were engaged and the purpose of the study described in detail. Community members subsequently participated in the design of an approach that was sensitive to local perceptions and social and cultural dynamics.



“[Study participants] will come up with solutions that are very innovative, that you would never have thought of. And that’s where the innovation happens.” (Key informant interviewee)



In some cases, local human resources were able to assist in the implementation of a research study. For example, in the eastern DRC, an International Medical Corps (IMC) research team trained women from local communities that were served by participating health facilities, such that they were able to conduct exit interviews with other women who had attended the facility to deliver.<sup>41</sup> This local connection was perceived to reduce the likelihood of response bias.

### Case Study 3: Engagement with affected populations

An evaluation of UNICEF’s Communities Care: Transforming Lives and Preventing Violence programme in Somalia and South Sudan relied heavily on local expertise throughout the study development and implementation phases.\* Local NGO partners mapped GBV service provision throughout the implementation phase. Local staff were trained in the safe and confidential conduct of focus group discussions, and completed an online research ethics course. Local staff also reviewed the focus group discussion questions, and proposed context and language-related adaptations. With the support of the local team, the focus group materials were translated and back-translated and piloted with community members to gauge understandability and the appropriate use of terminology. Local partners were integral to achieving trust and rapport with local communities, and were able to engage community leaders to assign a “community guide” to accompany each research assistant during community visits to identify potential participants.

\*; N. Glass, et al (2018), *Evaluating the communities care program: best practice for rigorous research to evaluate gender based violence prevention and response programs in humanitarian settings. Conflict & Health. 12:5*

## 4.3. Training of researchers

Almost all R2HC-funded studies have required that local researchers are trained, either because the intervention is new or because the proposed research tools and techniques are not known by local researchers. This investment in terms of capacity strengthening can be significant and is essential in all cases to ensure the quality of research. However, it should be noted that funds are not specifically made available in R2HC grants for capacity strengthening, but are incorporated into the cost associated with research activities.

In the absence of dedicated funding streams, an opportunity may be lost for the longer-term capacity strengthening of research groups, as opposed to the opportunistic training of local researchers as required to complete a specific research project.

An R2HC-funded research study that involved the measurement of hair cortisol levels required that fieldworkers were trained to implement the survey and collect biomarker data.<sup>42</sup> Rather uniquely, local hairdressers were employed and instructed on how to collect hair samples.

<sup>41</sup>Hynes M., Meehan K., Meyers J., et al. (2017), Using a quality improvement approach to improve maternal and neonatal care in North Kivu, Democratic Republic of Congo. *Reproductive Health Matters*. Vol. 25

<sup>42</sup>Dajani R., Hadfield K., van Uum S. et al. (2018), Hair cortisol concentrations in war-affected adolescents: A prospective intervention trial. *Psychoneuroendocrinology*. Vol. 89: 138–146



## 4.4. Testing new tools and techniques

Some studies reported use of methodological approaches that are relatively new, but that have only been applied in stable settings. One way of mitigating the risk of failure has been to test tools at a small scale and make adjustments. This has enabled researchers to make adjustments to tools and adapt them to the unpredictable contexts.

### Case Study 4: Demonstrating transferability of methods –systems dynamics analysis

An R2HC-funded research team working with UNRWA applied systems thinking methodologies to study health system functioning, which combined a case study design and systems dynamics analysis.

The proposal describes a step-by-step methodology, which has not been well documented in humanitarian settings. Completion of this study demonstrated feasibility of application of this methodology, and presented a series of lessons learnt. The established methodology follows five phases: scoping and elicitation of information to establish key themes and variables; group model building with key stakeholders; model refinement with statistical analyses and simulation modelling; prospective tracking of key variables for model validation; and synthesis of findings from the implementation of the aforementioned process in distinct study locations.

One study incorporated a testing phase before piloting a tool with patients. A psychological intervention in the form of an adapted, telephone-administered Common Elements Treatment Approach (t-CETA) was developed with both international and national experts, who trained local staff how to deliver CETA treatment. A small number of children were treated face-to-face using this approach, which allowed for the identification of contextually and culturally relevant components. The telephone adapted approach was later tested with a small number of children, while interviews with children, their caregivers, and mental health staff, helped to identify outstanding child protection, safety and privacy issues. The team later incorporated role-play between volunteers to help fine-tune components of the t-CETA.

Of note, one interviewee questioned the terms on which new tools were considered adapted to, or validated for use in, local contexts. Where power dynamics clearly exist, people may be less inclined to challenge scientists and their approaches.

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• “A lot of the tools are ... worst case scenario Western tools. Even  
• when they say they adapted it, validated it ... who did they do it with?”  
• (Key informant interviewee)

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Such maligned adaptation and validation processes can substantially skew the development of tools, and the results generated when such tools are subsequently applied.

## 5. Methodological Issues

### 5.1. Generalisability: a myth?

Research in humanitarian crises is heavily modulated by local contexts, which can be shaped by the security situation, the intensity of the crisis, levels of social unrest, economic and political factors, as well as community perceptions of the context and humanitarian response.

Few other research disciplines have been as affected by presumptions of generalisability of findings as has been the case for researchers working in humanitarian contexts. For any research study conducted in a specific context, it is unlikely that its findings are generalisable to another. In instances where knowledge may have applicability elsewhere, researchers should demonstrate how – if at all – their results may be relevant to other settings and crises, so as to facilitate the uptake of knowledge.

As such, research that acknowledges the specificities of a particular context have added value. While two R2HC-funded studies did incorporate a case study methodology, one interviewee felt that case studies were an under-used methodology, despite their usefulness in policy-making fora. Such a methodology captures complexity and implementation challenges, and often has a direct applicability. The case study-driven review of Basic Packages of Health Services (BPHS) in countries such as Afghanistan and Liberia were presented as pertinent examples of where evidence is translated to be used by policy makers to make strategic decisions. Instead, the pursuit of “hard” evidence and inter-contextual comparability may see researchers turn to more “robust” methodologies, such as RCTs.

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• *“The influence of [proponents of RCTs] has been to create a*  
 • *simplistic idea of an intervention, which totally ignores the social.”*  
 • (Key informant interviewee)

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A second interviewee recognised the importance of an inter-disciplinary framing of implementation challenges, in order to avoid proposing incomplete solutions to poorly conceptualised systemic issues.

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• *“It may be helpful to look with a more fundamental political and*  
 • *security lens, rather than with an implementation science lens ...*  
 • *The latter tends to peripheralise – or just be ignorant – of what*  
 • *the true obstacles are in these settings”* (Key informant interviewee)

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### 5.2. Dealing with biases

As demonstrated by the HHER, much of the existing evidence generated from humanitarian settings has emerged from refugee camps, which is an important selection bias. Such settings may be chosen for convenience insofar as population movements are limited, routine activities and basic services are easier to identify and define, and sampling and identification of potential participants can be more straightforward. However, it is increasingly recognised that humanitarian response is engaged in non-camp – “open” – contexts and in urban areas. As such, urban settings are an implementation and research priority for humanitarian practitioners and researchers alike, and require creative methodological approaches to respond to methodological challenges.

### Case Study 5: Responding to recruitment bias

In relation to the recruitment of participants, one R2HC-funded study testing an e-mental health intervention introduced an adapted method. Positive bias is often observed in relation to self-help, with highly motivated people more likely to volunteer to join an intervention group, which can generate discrepancies between the intervention and control cohorts. The research team proposed to counterbalance recruitment bias using a recruitment drive that incorporated posters, the internet, radio and the presence of health workers at clinics, in addition to randomisation of participants.

## 5.3. Methodological issues in sampling

Implementing a robust sampling strategy can pose a challenge in humanitarian settings in light of dynamic population movements, unclear population denominators, and difficulties identifying potential participants in urban, dispersed and rapidly changing contexts. These factors can have substantial implications for sample size determination, calculation and the eventual statistical power of findings.

One key informant interviewee described challenges associated with identification of the sampling frame and of individual units in a flood-affected area, due to poorly delineated, temporary shelters and overcrowding, along with issues related to the longer term follow up of a sample in the context of dynamic population movements. Another interviewee observed that despite sample identification and group randomisation during an RCT, contamination and variation in exposure to the intervention were issues due to the dynamic implementation context. For example, for one study implemented in Somalia, a number of different donors were funding nutritional interventions, with intervention packages varying during the study timeframe. Difficult questions were asked of attribution, given challenges associated with ensuring one study arm received the stated intervention exclusively, and given the propensity towards marked seasonal variation in nutritional outcomes in certain regions in Somalia.

For one R2HC-funded study exploring NCD care, the enrolment rate was not high enough to achieve statistical power. In order to increase the sample size, the research team modified their recruitment criteria without introduction of known bias by increasing the age range and enabling the recruitment of two individuals from the same household.

## 6. How Innovative is Humanitarian Research?

### 6.1. Innovative research methodologies: a myth

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 • *“This is framed impossibly. How can you be innovative  
 and stay rigorous?”* (Key informant interviewee)

All components of this review found that the research methods applied in humanitarian settings are rarely innovative or interpreted as such. While both the peer-reviewed literature and R2HC-funded research portfolio illustrate that a variety of study designs have been applied in humanitarian settings, methodologies do not frequently differ from those applied in stable settings.

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 • *“There are promises to “do things differently”. Research where  
 people do things differently isn’t the funded research. It tends  
 to be students leading ... some of the most interesting work  
 done is with [Masters] students”* (Key informant interviewee)

One key informant interviewee observed that established research institutions “know how to pass the test” when applying for research funding. Research expertise thus becomes further concentrated within a small number of institutions mainly based in the UK and the US. While research groups often look for ways to incorporate innovation, grant proposals are reviewed based on the likelihood that they can deliver robust research outputs. Instead, innovative methodologies that cannot be fully overseen require a certain degree of benefit of the doubt, curiosity, a progressive mindset, and a willingness to take risks among reviewers and grant-making bodies.

### 6.2. From innovative to relevant: asking the right questions

The value of research conducted in humanitarian crises is measured by practitioners, and ideally by the crisis-affected people who should benefit from knowledge generation, and not by the degree of self-declared innovation. Research should therefore relate to the needs of crisis-affected people, and the challenges they and humanitarian actors face in meeting those needs. Some respondents suggested that the knowledge production pyramid should be inverted, such that the needs of frontline humanitarian practitioners are prioritised. Another interviewee felt that groundbreaking innovation is most often achieved by implementers, while the scientific community remains slow to change, generally “reluctant to give up on the 95% [confidence intervals] before they can say anything.”

Some key informants preferred to talk of applied, operational evaluation as opposed to academic research to emphasise the value and importance of the direct operational applicability of research findings. There is a general consensus among practitioners and researchers that there is a need to better align the timeframes that define both programme implementation and research. Relatedly, where interventions concern issues related to protection and mental health, one interviewee noted that quantitative intervention logics are insufficient. Rather, research must attempt to better understand human behaviour and decision-making processes. Instead, the assumption that continues to underpin funding calls is that data is not being utilised correctly, which in turn accelerates the pursuit of “more tools and more quantitative outputs”.

The approach by which research proposals are solicited was also problematised. Open calls for proposals may encourage research driven by “let’s think of what we can do”, rather than “we’ve always wanted to know this, and now there is funding”. More directive research calls, shaped by an inclusive prioritisation exercise conducted with practitioners and researchers, may allow for a greater focus on unsolved questions and longstanding knowledge gaps. Two interviewees observed that researchers were more likely to have pre-determined their preferred methodology, which is then superimposed on to the chosen research question. Instead, a greater appreciation of the question that needs to be answered may reverse current logics; at present, “speaking of methodology first puts the cart in front of the horse”.

Relatedly, another interviewee observed that short-term humanitarian programming can make it difficult to fully understand contexts and identify potential research questions, which emerge over time with practice. A third interviewee observed that a focus on systemic challenges may allow for “leapfrog” innovation:

•••••

• “It is not so much about how we can make current mechanisms of  
 • provision more proficient. Rather we must take a step back and  
 • identify the underlying obstacles.” (Key informant interviewee)

•  
•  
•  
•••••

With such an approach, there may be a greater tendency towards innovative approaches, rather than greater efficiency in traditional mechanisms: “with innovative framing comes innovative methodologies”.

### 6.3. From innovative research methods to research methods innovatively applied

•••••  
 • *“It is less about the method itself, and more about how you use the method”* (Key informant interviewee)  
 •••••

The issue of quality is considered less in relation to the method used than how a method is applied. Two interviewees observed that in order to develop entirely innovative methodologies, research that simultaneously utilises different methodologies may be required to prove that new approaches are equally valid.

Researchers working in the humanitarian sector are a small community. Research expertise in the application of certain methodologies is essential to ensure high quality research. The experience of the researchers who have worked in, and can work in, difficult contexts must be harnessed: that is those individuals who are able to adapt to conducting research in changing and dynamic contexts, and to identify solutions that minimise study disruption, while preserving the wellbeing and safety of local researchers and populations.

#### Case Study 6: Adaptation and solution-orientated thinking in dynamic environments is key

One research team that was awarded an R2HC grant had initially proposed the stepped-wedge implementation and evaluation of a ketamine-based anaesthetic intervention. Nationwide healthcare provider strikes, and the impact of these strikes on the wider health system, made it difficult to employ this methodology due to logistical impediments that made the step-wise roll-out of the intervention and periodic data collection too complicated. It also became too difficult to ensure that the necessary clinical variables remained constant, as per the requirement of a true stepped-wedge trial.

During the inception phase the research team and their partners decided to alter the study design such that the anaesthetic package was launched at all study sites simultaneously, with historical data used as an additional data source for comparison.

In another study funded by R2HC addressing the impact of cash and vouchers on nutrition outcomes in Somalia, a difference-in-difference analysis was used to assess change over time in each intervention group (two arms with two different interventions). This analysis was beneficial given the inability to randomise and given that households had received other interventions prior to enrolment. Where possible, analysis controlled for baseline characteristics at enrolment and both unadjusted and adjusted differences were reported.

## 6.4. Learning from stable settings

Applied and operational research is integral to the pursuit of evidence-informed humanitarian action. However, it is important to first identify whether a research project is likely to have relevance, and to gauge the potential uptake of findings by humanitarian organisations. As mentioned, close relationships with practitioners are key (e.g. Ministry of Health, humanitarian agencies) to ensure that research studies are driven by recognised knowledge gaps and localised implementation challenges.

As previously outlined, conducting research in humanitarian settings can be challenging. A great deal of knowledge has already been generated in stable settings, and research and evidence from such settings should always be considered in the design and development of a research study.

•••••  
 • *“Some research could be trialled elsewhere ... then it’s more*  
 • *a question of translating interventions: how acceptable,*  
 • *feasible and quick to deploy?”* (Key informant interviewee)

It may also be feasible to conduct a pilot in a stable setting before considering roll-out of a more comprehensive study in a logistically challenging context. What remains specific to humanitarian settings is the mode and means of delivery, for which implementation research has substantial added value.

## 6.5. Humanitarian research: basics first, then innovate

Routine data collection in humanitarian settings is often of a poor quality: incomplete, missing or inaccurate. The data collected rarely enables analysis of programme impact or outcomes. Practitioners often poorly document baseline indicators, i.e. conduct a proper baseline study before implementation of an activity. Where available and of a good quality, routine data (e.g. medical records, health facility data, surveillance data) and largescale surveys (e.g. Demographic Health Surveys) can help to facilitate retrospective analysis. Such data can also be used during the implementation of an intervention to capture changes occurring at the facility level e.g. coverage of services, quality of care, and health facility assessments. There remains an urgent need for the research and practitioner communities to engage on the issue of indicators and variables, and to jointly invest in processes that more readily allow for impact evaluation.



## CONCLUSION AND RECOMMENDATIONS

This review provided insight into the choice of research methods as reported in the peer-reviewed literature and from R2HC-funded research studies. Additional insights were drawn from experts in the research and implementation communities.

While new and innovative methodologies were not identified as such by this review, adaptive approaches were recognised at various stages in the research process. Conducting research in challenging and unpredictable contexts has required that mechanisms for flexible and agile programming and research implementation be introduced. Researchers have demonstrated an ability to incorporate methodological adaptations, which is often a demonstration of the capacity of researchers to analyse the context, master different methodological approaches and tools, and actively search for adaptive solutions.

The use of electronic data collection tools, investment in local researchers and research networks, the use of mixed methods, and relatedly the triangulation of data using different sources of information, the testing of tools and interventions prior to full study implementation, and the anticipation of alternative research implementation and management processes, have all proven valuable.

Following this review, we propose a series of recommendations that are likely to benefit humanitarian researchers, and grant-making bodies such as Elrha.





# RECOMMENDATIONS FOR GRANT-MAKING BODIES

## 1. Create a neutral platform where methodological challenges and solutions are shared between researchers

Elrha offers researchers the opportunity to document challenges faced during the implementation of research and solutions identified. However, summary reports are limited in detail, which may be a consequence of the fact that fund-recipients are reporting to the donor.

Grant-making bodies may wish to consider the sponsorship of workshops where researchers have the opportunity to openly discuss challenges and solutions. This space could also take the form of an online platform where issues and solutions are discussed, and which would be more inclusive of a global research community.

## 2. Enable reporting forms to capture methodological adaptations made by researchers

Grant makers should ensure that research proposals and risk assessment templates and reporting forms include dedicated sections with questions related to scenarios and adaptations anticipated by researchers.

## 3. Proposals should be reviewed using methodological checklists that correspond to the study design

In order to achieve greater objectivity, research proposal Funding Committee reviewers should use a common methodology checklist to assess the methodological rigour of each proposal. Two example checklists were developed during this review, and could be expanded such that a dedicated checklist exists for specific study methods (Annex 5, Annex 6).

## 4. Include a specific budget line for the training of local researchers

Almost all studies include a training component, which is often essential to the overall quality of a study and its research outputs.

While funding may be available for the training of research teams in order to implement a specific research study, dedicated funding streams are still largely unavailable for the purpose of wider capacity strengthening for research teams, such as training in data analysis software. Grant makers should facilitate inclusion of budget lines for this purpose to enable the critical capacity strengthening of local researchers.

# RECOMMENDATIONS FOR RESEARCHERS

## 5. The use of mixed methods should be encouraged

Mixed methods approaches are often cited by researchers and are becoming more popular in humanitarian research circles, as they allow for triangulation of data and enhanced reliability of findings.

To ensure this new buzzword in the humanitarian research lexicon achieves its full potential, such approaches must be applied appropriately by teams with the expertise required to rigorously apply each chosen methodology.

Grant-making bodies must also actively support research that incorporates a mixed methods component, where the added value of such an approach is clearly justified.

## 6. Test and pilot methods before going full scale

Several research teams acknowledged that the testing of tools and methods with local researchers, and in the local context, was beneficial and allowed teams to refine their methods and anticipate changes during the implementation phase.

Prior pilots in stable settings or in a humanitarian context at a smaller scale should be more explicitly stated in research proposals, while grant-making bodies should make available funding to allow for small-scale pilots or formative research in advance of the roll-out of a comprehensive research study.

## 7. Engagement and partnership with local researchers and collaborators is essential

The involvement of local researchers and local populations in the design, development and implementation of research studies can not only positively impact the quality of research outputs, but is a demonstration of good research practice.

Building a trusted relationship with local researchers will enhance transparent communication and timely adaptations to the context. Collaboration with local researchers, and engagement with the intended study population must be encouraged, if not made mandatory by grant-making bodies.

## 8. Documenting methodological challenges and solutions

This study shows that researchers do not extensively describe and justify the adaptations they make during the course of their work. In the diverse and complex context that define humanitarian crisis contexts worldwide, it is important that researchers share and discuss challenges and lessons learnt. To do so, researchers must describe and analyse the methodological challenges they face and explain the adaptations they introduce. Such information should be made available on a platform that is accessible to researchers globally.

## 9. Utilisation of electronic management tools hold promise where access is difficult

Electronic management tools for the purpose of remote monitoring, supervision, and data management are increasingly utilised, particularly in unstable settings, and should be considered where access for certain members of the research team may be limited.



# RECOMMENDATIONS FOR HUMANITARIAN PRACTITIONERS

## 10. Identify opportunities for the utilisation of existing data where possible

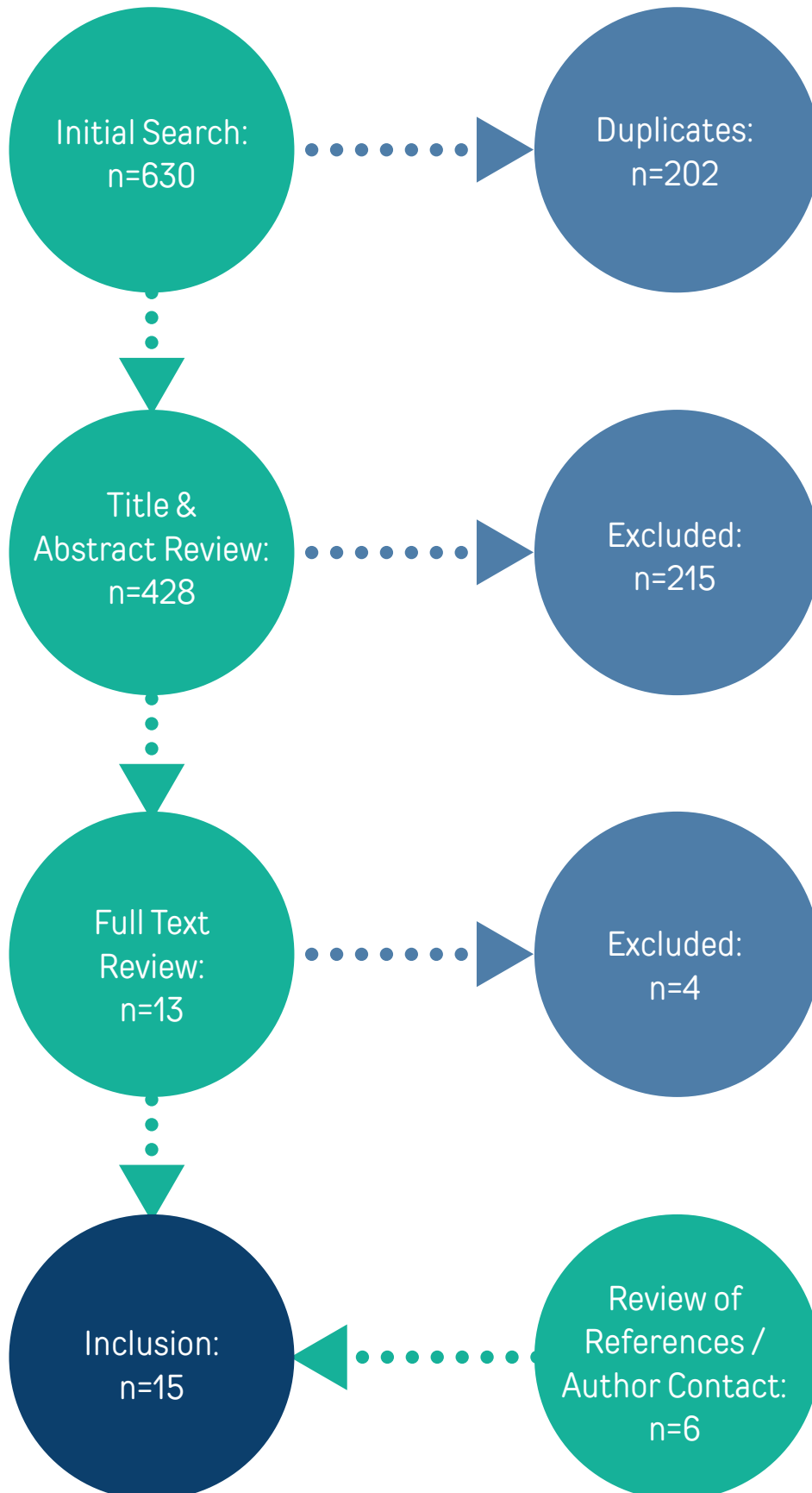
The utilisation of existing data is a matter of both ethical importance and operational effectiveness. All forms of data collection in humanitarian contexts present possible risks, and place an additional burden on affected people, who may be recovering from difficult and traumatic events. Where data is collected, it is important that it is utilised to its full effect, foremost for the benefit of the population from which it has been taken, and secondarily for wider knowledge generation and uptake where appropriate.

Humanitarian response organisations should work closely with researchers to ensure that systems are in place for the ethical generation of good quality routine data. Implementing organisations should also ensure that, where data already exists, it is used to inform programming and to identify knowledge gaps that may be bridged with further targeted research.

## Annex 1: Key Informant Interviewees

N	Name	Affiliation
1	Alistair Ager	Queen Margaret University
2	Emmanuel Baron	Epicentre
3	Christina Bennett	Overseas Development Institute
4	David Beran	University Hospital Geneva
5	Sara Casey	Columbia University Mailman School of Public Health
6	Francesco Checchi	London School of Hygiene & Tropical Medicine
7	Iza Ciglenecki	Médecins Sans Frontières
8	Sandro Colombo	World Health Organisation
9	Rana Dajani	Hashemite University
10	Jai Das	Aga Khan University
11	Shannon Doocy	Johns Hopkins Bloomberg School of Public Health
12	Marc Dubois	Independent
13	Fouad M. Fouad	American University of Beirut
14	Michelle Gayer	International Rescue Committee
15	Rebecca Grais	Epicentre
16	Lara Ho	International Rescue Committee
17	Natasha Howard	London School of Hygiene & Tropical Medicine
18	Michelle Hynes	Centers for Disease Control
19	Jo Mulligan	U.K. Department for International Development
20	Vinh Kim Nguyen	Graduate Institute, Geneva
21	Mark Van Ommeren	World Health Organisation
22	Enrico Pavignani	Independent
23	Sophie Read-Hamilton	Independent
24	Bayard Roberts	London School of Hygiene & Tropical Medicine
25	Les Roberts	Columbia University Mailman School of Public Health
26	Rodolfo Rossi	International Committee of the Red Cross
27	Leonard Rubenstein	Johns Hopkins Bloomberg School of Public Health
28	Kevin Savage	World Vision International
29	Andrew Seal	University College London
30	Neha Singh	London School of Hygiene & Tropical Medicine
31	Egbert Sondorp	KIT Royal Tropical Institute
32	Paul Spiegel	Johns Hopkins Bloomberg School of Public Health
33	Ben Taylor	Evidence Aid
34	Carrie Teicher	Epicentre
35	Fiona Terry	International Committee of the Red Cross
36	Caitlin Wake	Overseas Development Institute
37	Courtney Welton-Mitchell	University of Colorado
38	Paul Wise	Stanford University
39	Rony Zachariah	World Health Organisation

## Annex 2: Peer-Reviewed Article Screening Process



## Annex 3: Narrative Synthesis of Peer-Reviewed Literature

### Violence Against Women & Girls

Three papers presented details of a longitudinal mixed methods household trial to assess the impact of UNICEF’s Communities Care: Transforming Lives and Preventing Violence programme.<sup>43,44,45</sup> The programme, which began in 2012 in Karaan and Bondhere districts, Somalia and Yei and West Gogrial counties, South Sudan, was subject to an evaluation in 2016. One intervention and one delayed control site were identified in each country. A comprehensive inception phase allowed researchers the opportunity to train local data collectors in the safe and confidential conduct of focus group discussions and individual key stakeholders. Prior to the in-person training, research staff completed an additional online research ethics training. Focus group discussions and stakeholder interviews informed a review of social norms in each community, which informed the development of social norms measures for GBV. Research assistants were accompanied by “community guides”, selected by community authorities, who assisted local research staff in navigating local communities. Every third household was approached and, if the member of the household met the inclusion criteria, were asked to participate. Serial interviews were taken, with follow-up over the course of a 12-month period. Due to the prolonged follow-up period, detailed contact information was collected, with an SMS reminder sent ahead of scheduled appointments. Responses were recorded on an iPad to reduce the logistical burden of paper-based data collection, and to allow for real-time data management. In Somalia, insecurity in the district of Yaqshid (an intervention location) hindered programme implementation, while an influx of internally-displaced persons (IDPs) in the district of Wajadir (a control location) saw a corresponding increase in cases of GBV and the engagement of a diversity of other organisations. As a result, both locations were subsequently removed from the study analysis, with a reduction in the overall sample size.

An IRC Creating Opportunities through Mentoring, Parental involvement, and Safe Spaces (COMPASS) programme was implemented and evaluated in Ethiopia, the DRC and Pakistan between 2014 and 2017.<sup>46</sup> In Ethiopia (results not reported) and the DRC the programme was evaluated in the form of two cluster RCTs. In the DRC 35 groups of girls (grouped based on geographic proximity or language) in 14 villages were enrolled. 18 clusters were randomised to receive treatment (Adolescent Girl Safe Space and life skills programming (AGSS) plus caregiver discussion groups), while 17 were wait-list controlled (AGSS only).<sup>47</sup> Self-administered Audio Computer Administered Self Interviews were used for sensitive violence-related questions (and may achieve reduced social desirability bias), while face-to-face Computer-Administered Personal Interviews were used for non-sensitive questions. Research implementation benefited from an in-country programme team, which was able to contextualise the study materials. The process of contextualisation, piloting, and the review of interview languages and translation of materials extended the inception period from three months to almost one year. While sisters were allocated to the same study arm, the authors noted that treatment and control groups in the same villages may have led to cross-contamination.

### Mental Health & Psychological Support

A proposed four-arm randomised control trial in Kurdistan became two distinct studies after the research team identified population-based differences in religiosity, political conservativeness, and trauma exposure between the proposed study sites.

<sup>43</sup>Read-Hamilton S., Marsh M. (2016), The Communities Care programme: changing social norms to end violence against women and girls in conflict-affected communities. *Gender & Development*. Vol. 24 (2): 261-276

<sup>44</sup>Glass N., Perrin A., Clough P., et al. (2018), Evaluating the Communities Care program: best practice for rigorous research to evaluate gender based violence prevention and response programs in humanitarian settings. *Conflict & Health*. 12:5

<sup>45</sup>Glass N., Perrin N., Marsh M., et al. (2019), Effectiveness of the Communities Care programme on change in social norms associated with gender-based violence (GBV) with residents in intervention compared with control districts in Mogadishu, Somalia. *BMJ Open*. 9:e023819

<sup>46</sup>Falb KL., Tanner S., Ward L., et al. (2016), Creating opportunities through mentorship, parental involvement, and safe spaces (COMPASS) program: multi-country study protocol to protect girls from violence in humanitarian settings. *BMC Public Health*. 16: 321

<sup>47</sup>Stark L., Seff I., Asghar K., et al. (2018) Building caregivers’ emotional, parental and social support skills to prevent violence against adolescent girls: findings from a cluster randomised controlled trial in Democratic Republic of Congo. *BMJ Global Health*. 3: e000824

One study evaluated the impact of a supportive counselling programme in Dohuk governorate<sup>48</sup> while a second study evaluated two psychotherapeutic interventions, Behavioural Activation Treatment for Depression (BATD) and Cognitive Processing Therapy (CPT), in Erbil and Sulaimaniyah governorates.<sup>49</sup>

In Dohuk governorate, 159 people were randomised to immediately receive the supportive counselling intervention, while 50 people were waitlist controlled for a period of three to five months. Waitlist control participants were followed up monthly to monitor for any change of symptoms. A Kurdish psychiatrist acted as clinical supervisor throughout the study, who also conducted monthly on-site supervision and weekly telephone check-ins to ensure fidelity to the treatment model. Fearing loss to follow up of individuals who dropped out of the trial, some follow-up interviews were conducted by staff unblinded to a participant's treatment status. There were some delays between baseline and follow up assessments due to logistical and security constraints, which were controlled. In Erbil and Sulaimaniyah, 281 individuals were enrolled to receive either BATD or CPT, with 215 individuals randomised to receive immediate treatment, and 66 waitlist controlled. Those waitlist controlled were enrolled after approximately five months, with monthly contact in the intervening period to monitor symptomatology. Both the BATD and CPT interventions were adapted for low literacy levels and para-professional application. The instruments used to measure symptoms were adapted to the local context based on a preceding qualitative study. Training and supervision of community mental health workers (CMHW) was delivered using the Apprenticeship Model, with two weeks of initial training for CMHWs and supervisors, ongoing training and supervision from local supervisors, who in turn received weekly training and oversight from international colleagues by Skype, phone, or email.

An R2HC-funded study examined hair cortisol concentration as a biological marker of stress and trauma amongst Syrian refugee and Jordanian host-community youth.<sup>50</sup> Cortisol data was collected for 727 adolescents, and monitored over the course of an 8-week Advancing Adolescents intervention delivered by Mercy Corps, described in greater detail in an earlier paper.<sup>51</sup> Youth were enrolled between 2014 and 2016, who then participated in activities by a profound stress attunement (PSA) framework over eight weeks. Of 817 enrolled adolescents, 214 participated in a quasi-experimental trial during the first programmatic cycle. Randomisation was not possible for ethical reasons due to uncertainty of renewal of the implementing partner's funding. As such, youth were enrolled based on their availability, while others were waitlisted due to the unavailability of trained coaches. In cycle two, after programmatic funding was renewed, 603 youth participated in a fully randomised study. Insecurity, stress, and mental health were assessed over time in both the treatment and control groups.

In Lebanon, the effectiveness of SMART-3RP (Stress Management Relaxation Response Resilience) training delivered to Lebanese social workers and field workers on levels of stress was assessed in the form of a longitudinal mixed methods study.<sup>52</sup> All personnel receiving the training were asked if they would like to participate in the research, with 100 of the 120 participants consenting to their involvement. The authors describe high rates of participant drop-out, as human resources were limited and participants often had to choose between attending the training (and by extension participating in the research) or providing assistance to Syrian refugees. Almost 50% of the participating staff had dropped out by month 12. The authors describe opting for a longitudinal study as opposed to an RCT or staggered inclusion due to ethical concerns, and the immediate need to have trained personnel to respond to the needs of Syrian refugees in affected areas.

<sup>48</sup>Bass J., Murray SA., Mohammed TA., et al. (2016), A Randomized Controlled Trial of a trauma-informed support, skills, and psychoeducation intervention for survivors of torture and related trauma in Kurdistan, Northern Iraq. *Global Health: Science & Practice*. Vol. 4 (3): 452-466

<sup>49</sup>Bolton P., Bass JK., Zangalla GAS., et al. (2014), A randomized controlled trial of mental health interventions for survivors of systematic violence in Kurdistan, Northern Iraq. *BMC Psychiatry*. 14: 360

<sup>50</sup>Dajani R., Hadfield K., van Uum S. et al. (2018), Hair cortisol concentrations in war-affected adolescents: A prospective intervention trial. *Psychoneuroendocrinology*. Vol. 89: 138-146

<sup>51</sup>Panter-Brick C., Dajani R., Eggerman M., et al. (2017), Insecurity, distress and mental health: experimental and randomized controlled trials of a psychosocial intervention for youth affected by the Syrian crisis. *The Journal of Child Psychology & Psychiatry*. Vol. 59 (5): 523-541

<sup>52</sup>Chemali Z., Borba CPC., Johnson K., et al., (2017), Humanitarian space and well-being: effectiveness of training on a psychosocial intervention for host community-refugee interaction. *Medicine, Conflict & Survival*. Vol. 33 (2): 141-161



Children who had experienced traumatic events were recruited from IDP sites in Bangui and Sibut, Central African Republic (CAR), to participate in a series of five weekly psychoeducation sessions.<sup>53</sup> The intervention was preceded by two weeks of training for local psychosocial workers, who were supported by expert psychologists throughout the course of the study. Traumatic symptoms were measured at the time of admission, and following the five-week intervention.

## Sexual & Reproductive Health

Data from CARE's Supporting Access to Family Planning and Post-Abortion Care in Emergencies (SAFPAC) was described in one paper,<sup>54</sup> with the programme outlined in greater detail in an accompanying paper.<sup>55</sup> The SAFAC programme provided: 1) competency-based training, along with follow up clinical assessment and coaching for service providers; 2) improved supply chain management for family planning commodities; 3) regular facility and provider supervision; and 4) community mobilisation to raise awareness of family planning and address barriers to service uptake. Project service delivery data was collected between 2010 and 2013, though the authors acknowledge that the data was collected for the 'purpose of continuous quality improvement, not for the purpose of conducting systematic research in a strictly defined model.'<sup>56</sup> While the data illustrated an increase in the number of people using new contraceptive methods, and specifically those using long-acting reversible contraceptives (LARC), the authors further acknowledge that the ability to identify causal relationships or to make generalisable conclusions is limited as the findings are from routine monitoring data rather than a randomly sampled representative group with a control.

## Maternal & Neonatal Care

A longitudinal quasi-experimental mixed methods study was conducted in North Kivu, eastern DRC to assess the impact of a quality improvement (QI) methodology on the active management of third stage of labour and essential newborn care.<sup>57</sup> A convenience sample was chosen based on locations where partner NGO International Medical Corps (IMC) had existing activities. Baseline evaluations were conducted over an initial 6-week period. Study facilities were split, with all facilities receiving clinical training, while an enhanced intervention group applied a QI methodology, involving QI teams in each facility, supported by coaches. During a testing period, health facility staff identified possible QI actions and collected process data to identify whether the action led to quality improvement. Data was collected in the form of patient exit interviews conducted by women from the local community who had been trained by the IMC research team.

## Food Security

Repeated household surveys were used to evaluate the effect of three different types of food assistance – in-kind food, food vouchers, and unrestricted vouchers – in Harem District of Idlib Governorate, northern Syria.<sup>58</sup> Participants of each transfer modality were randomly selected, with an independent sample used at endline. Data was collected by GOAL national staff, who had prior data collection experience. The authors noted significant variation between study populations at baseline and endline, acknowledging the 'fluid and unpredictable nature of the settings in which [humanitarian interventions] are implemented'.<sup>59</sup> Delays in endline data collection resulted from insecurity, while it was also not possible to control the humanitarian assistance received by different households.

<sup>53</sup>Bozio E., Bonal N., Galliot C., Bizouerne C. (2018), Psychological device for groups: Clinical experience with traumatized children in Central African Republic. *Neuropsychiatrie de l'Enfance et de l'Adolescence*.

<sup>54</sup>Curry DW., Rattan J., Huang S., Noznesky E. (2015), Delivering high-quality family planning services in crisis-affected settings II: results. *Global Health: Science & Practice*. Vol. 3 (1): 25 – 33

<sup>55</sup>Curry DW., Rattan J., Nzau JJ., Giri K. (2015), Delivering high-quality family planning services in crisis-affected settings II: program implementation. *Global Health: Science & Practice*. Vol. 3 (1): 14 – 24

<sup>56</sup>Curry DW., Rattan J., Huang S., Noznesky E. (2015), Delivering high-quality family planning services in crisis-affected settings II: results. *Global Health: Science & Practice*. Vol. 3 (1): 25 – 33

<sup>57</sup>Hynes M., Meehan K., Meyers J., et al. (2017), Using a quality improvement approach to improve maternal and neonatal care in North Kivu, Democratic Republic of Congo. *Reproductive Health Matters*. Vol. 25

<sup>58</sup>Doocy S., Tappin H., Lyles E., et al. (2017), Emergency food assistance in northern Syria: an evaluation of transfer programs in Idlib Governorate. *Food and Nutrition Bulletin*. Vol. 38 (2): 240 – 259

<sup>59</sup>Ibid.



## Annex 4: R2HC Calls 1–4 Study Extraction Table

Call	PI	Country(s)	Context	Phase	Population	Camp?	Thematic	Study Design (planned)	Pre-pilot in this context (planned)	Mixed Methods Component (planned)	Changes (focus on methodological)
1	Courtney Welton-Mitchell, Leah James	Multi: Haiti, Nepal	Environmental disaster	Acute	General pop.	No	Mental Health	Longitudinal RCT	Yes (conducted prior to R2HC)	Yes: RCT and FGDs	Increased sample size to account for attrition; cultural adaptation incorporated; in Haiti, interviews conducted in a safe location rather than households due to security concerns; delays to data collection in Nepal due to crisis events
1	Wietse Tol	Tanzania	Camp (conflict affected)	Protracted / chronic (>10 years)	Refugees (Congolese)	Yes	Intimate partner violence (IPV)	Individually randomised, parallel group, waitlist-controlled trial	Yes	Yes: qualitative interviews; RCT	Recruitment site changed to women's groups from local facilities; second post-intervention follow-up replaced by a process evaluation; exit interviews incorporated
1	Thomas Handzel	Ethiopia	Refugee camp (conflict affected)	Protracted / chronic (>2 years)	Refugees (Somali)	Yes	WASH	Mixed methods longitudinal, two cross-sectional	No	Yes: longitudinal performance evaluation, cross-sectional surveys and qualitative methods (FGDs to inform the KAP survey)	Qualitative component not feasible due to researcher travel constraints; revised performance evaluation in a controlled setting due to sample quality issues and travel restrictions
1	Shannon Doocy	Lebanon	Informal tented / collective shelters, rural / urban (conflict affected)	Protracted / chronic (>2 years)	Refugees (Syrian)	No	NCDs	Longitudinal – cohort monitoring	Yes (of tools)	Yes: structured and semi-structured interviews, medical records review	Nil notable reported
1	Mark Van Ommeren, Saeed Farooq	Pakistan	Peri-urban (conflict affected)	Protracted / chronic	Predominantly general population	No	Mental Health	Single-blind RCT & semi-structured KIIs	Yes (conducted prior to R2HC)	Yes: RCT and key informant interviews	Nil notable reported
1	Kevin Savage, Alastair Ager	Multi: Uganda, Jordan, Nepal	Resettlement camp (Congolese refugees); urban, non-camp (Syrian refugees); acute disaster	Protracted / chronic; proposed acute	Refugees (Congolese, Syrian); General pop.	Mixed	Child Protection / Mental Health	Longitudinal impact studies – survey interviews; participative ranking and systems mapping	No	Yes: longitudinal impact studies with qualitative components	Nil notable reported

2	Silke Pietzsch	Pakistan	Predominantly rural (post-flood)	Post-flood / stable chronic	General population	No	WASH	Non-blind RCT and in-depth interviews	No	Yes: multi-arm RCT and interviews	Nil notable reported
2	Cécile Bizouerne	Nepal	Rural, non-camp (chronic nutritional crisis)	Stable chronic	General population	No	Mental Health & Nutrition	Cluster RCT and cost-effectiveness analysis	No	Yes: cluster RCT and cost-effectiveness	Nil notable reported
2	Claire Horwell	Multi: Indonesia, Japan, Mexico	General population (pre-environmental)	Chronic / acute	General population	No	Respiratory	Parallel blinded RCT, laboratory testing, quant. questionnaire and interviews	Yes (of surveys)	Yes: RCT and qualitative assessment	Clinical trial not conducted – protocols for epidemiological studies during future eruptions developed
2	Maia Butsashvili	Georgia	Settlements (conflict affected)	Chronic / stable	IDPs	No	Health financing	Retrospective cohort study	No	No	Nil notable reported
2	Michelle Hynes	DRC	Rural conflict-affected	Chronic	IDPs and host	No	Maternal and neonatal health	Longitudinal, quasi-experimental mixed methods study	No	Yes: key informant interviews, exit interviews, FGDs, record abstraction	Mid-point evaluation withheld; refined outcome indicators; interviews withheld as conducted during another component of the intervention
2	Marni Sommer	Multi: Tanzania, Myanmar, Lebanon	Peri-urban settlement, and IDP camp and refugee camp (conflict-affected)	Chronic	Refugees (Burundian, Congolese, Syrian) and IDPs	Mixed	SRH	Qualitative analysis, tool development, mixed methods process evaluation	No	Yes	Mali switched to Tanzania (security, capacity and crisis phase considerations)
2	Mark Van Ommeren, Wietse Tol	Uganda	Refugee camp (conflict affected)	Chronic	Refugees (South Sudanese)	Yes	Mental Health	Cluster RCT; qualitative process evaluation	Yes	Yes: RCT, qualitative evaluation	Only women recruited; increase in RCT sample size; removal of one process evaluation; change to follow-up time points
2	Catherine Panter-Brick	Jordan	Peri-urban (conflict affected)	Chronic	Refugees (Syrian)	No	Mental Health	Randomised impact evaluation; Quasi experimental trial followed by RCT	Yes (R2HC seed funding)	No	Nil notable reported
2	Courtney Welton-Mitchell, Leah James	Nepal	Environmental disaster (earthquake)	Acute	General population	No	Mental Health	Step-wedge quasi-experimental	No	No (focus-group discussions included later)	Change to data collection time points; unable to include people with severe mental health needs as planned due to identification issues; focus group discussions incorporated

3	Lisa Schwartz, Matthew Hunt	Multi: Guinea, Rwanda, Jordan, Nepal, Haiti, Philippines	Multiple	Multiple	General population and humanitarian workers	No	Palliative care	Critical interpretive synthesis, survey, interviews	No	Yes: critical interpretive synthesis, survey, semi-structured in-depth interviews	Interviewee sample size increased
3	Elysée Nouvet, Lisa Schwartz	Multi: Guinea, Liberia and Sierra Leone	Outbreak (Ebola)	Post-crisis	Ebola survivors, implementers and researchers	No	Ethics	Qualitative (in-depth, semi-structured interviews) and literature review	No	No	Interviewee sample size increased
3	Alastair Ager	Multi: Syria, Lebanon, Jordan	Conflict affected	Protracted; Acute	Refugees (Palestinian)	Mixed	Health system resilience	Systems dynamics analysis with case studies	Yes (conducted prior to R2HC)	No	Nil notable reported
3	Marian Tankink, Joop De Jong	Multi: Sierra Leone & Liberia	Outbreak (Ebola)	Acute	Ebola response teams (health personnel, inter-sectoral)	No	Mental Health	Cluster randomised trial and qualitative methods	No	Yes: retrospective analysis; in-depth interviews; randomised trial	Removal of beneficiaries as a research group
3	Sandra Krause, Courtland Robinson	Multi: Lebanon, Ethiopia, Myanmar	Peri-urban settlement, and IDP camp and refugee camp (conflict-affected)	Protracted	IDPs in Myanmar, refugees (South Sudanese, Syrian)	Mixed	Child marriage	Cross-sectional survey (randomised, cluster design); qualitative evaluation (FGDs, interviews)	Yes (conducted prior to R2HC)	Yes: cross-sectional survey and qualitative methods	Change of project location in Lebanon; Sampling change in Lebanon (cluster to snowball)
3	Thomas F. Burke	Kenya	Rural and peri-urban (conflict affected)	Protracted	General population & refugees	No	Anaesthesia	Stepped wedge trial & qualitative evaluation	No	Yes: step wedge trial and mixed methods evaluation (semi-structured questionnaires)	Health worker strikes: step wedge component dropped. Proceeded with implementation with historical control data
3	Leonard Rubenstein	Syria	Conflict affected	Acute	General population	No	Ethics	Case studies with qualitative methods	No	No	Nil notable reported
3	Junaid Razzak	Pakistan	Heatwaves	Acute	General population	No	Heat management	Cluster RCT	No	No	Nil notable reported
3	Donal O'Mathuna	Multi: Nepal, Afghanistan, Ethiopia, South Sudan	Multiple	Protracted	General population; IDPs; Refugees (Eritrean, South Sudanese)	Mixed	Ethics	Case studies; qualitative assessment; tool development (and literature review)	Yes (conducted prior to R2HC)	No	Withdrawal of one site due to an acute humanitarian crisis. Delays negotiating partnerships

4	Junaid Razzak	Multi: Pakistan, Honduras, Nigeria	Multiple	Preparedness; Acute	General population	No	Health Systems	Tool development (Delphi consensus, direct observation) & qualitative assessment (and literature review)	Yes	No	Nil notable reported
4	Sara Casey	Multi: South Sudan & Afghanistan	Armed conflict	Protracted; Acute	General population	No	Post-abortion care	Retrospective analysis; qualitative assessment (FGDs, interviews); facility assessment	No	Yes: retrospective analysis; qualitative; facility assessment	Population moved between two sites in South Sudan – interviewed in both locations; increase in FGD size in Afghanistan
4	Daniele Lantagne	Multi: Bangladesh, DRC, Haiti	Multiple: cholera prevention	Protracted	General population	No	WASH	Literature review; laboratory testing; qualitative assessment; "field" effectiveness (household survey, FGDs, interviews, water and surface testing)	No	Yes: laboratory efficacy testing; multi-method effectiveness evaluation	Reduced sample size for household spraying survey
4	Mark van Ommeren	Lebanon	Urban and peri-urban (conflict-affected)	Protracted	Refugees (Syrian)	No	Mental Health	RCT & qualitative assessment	Yes (and additional piloting funded prior to R2HC)	Yes: pilot RCT; full RCT; qualitative assessment (interviews)	Minimal changes to the intervention, follow-up, and randomisation software
4	Michael Pluess	Lebanon	Urban, rural (some camp) (conflict-affected)	Protracted	Refugees (Syrian children)	Mixed	Mental Health	RCT & qualitative assessment	No	Yes: RCT; qualitative assessment (interviews)	Delays led to a smaller study sample size; Cultural issues, barriers requirement adaptation of assessment and treatment; Pre-pilot testing of intervention
4	Shannon Doocy	Multi: Jordan & Lebanon	Non-camp (conflict-affected)	Protracted	Refugees (Syrian)	No	Cash transfer (NCDs)	Cohort study, cross-sectional & qualitative assessment	No	Yes: qualitative (FGDs), cross-sectional, quasi-experimental cohort	Delays while an updated beneficiary dataset from UNHCR awaited; Expanded eligibility criteria
4	Richard Bryant	Jordan	Informal settlements (conflict-affected)	Protracted	Refugees (Syrian youth)	No	Mental Health	RCT & qualitative assessment	Yes	Yes: qualitative assessment and ethnography; pilot RCT; RCT; process evaluation (interviews)	Change to symptom checklist; Negotiations to incorporate pre-post hair cortisol levels (pending)
Food & Nutrition	Kevin Savage, Shannon Doocy	Somalia	Rural	Protracted	General population and IDPs	No	Food & Nutrition	Quasi-experimental	Yes (of tools)	Yes: quasi-experimental, plus secondary programme monitoring data analysis and FGDs	Intervention arm change due to change to market food availability; transfer amount changes due to fluctuation in food prices; two rather than three data collection rounds due to early end of intervention
Food & Nutrition	Andrew Seal	Somalia	Peri-urban	Protracted	IDPs	Yes	Food & Nutrition	Qualitative: case narratives, semi-structured interviews, FGDs, participatory appraisal techniques, observation	No	No	Narrative approach adopted
Food & Nutrition	Naoko Kozuki	Multi: Somalia (Niger, Nigeria, South Sudan, Yemen)	Urban	Protracted	General population and IDPs	No	Food & Nutrition	Cohort, semi-structured interviews, case study policy analyses (Niger, Nigeria, South Sudan, Yemen)	No	Yes: cohort, interviews, policy analysis	Nil notable reported

# Annex 5: Qualitative Research Assessment Tool

## Theoretical Issues

1. Is a qualitative approach justified by the researcher? Does the research seek to investigate the what and why?
  - The choice of methodology is fully justified in relation to the topic studied
  - The choice of the methodology is explained in part
  - The choice of methodology is not justified
2. Is the purpose of the study adequately described and justified?
  - The purpose of the study is explained and justified with reference to programmatic or policy gaps
  - The purpose of the study is explained but not linked to any programmatic or policy issue
  - The purpose of the study is not explained

## Study Design

3. Is the context of the study adequately described?
  - The researcher describes in detail the specificities of the context and its effects on public health and service delivery
  - The researcher describes the general context without reflecting on the effect on public health or service delivery
  - No description of the context
4. Are the research questions clearly defined?
  - The research questions are explicit and correspond to knowledge gaps
  - The research questions are listed but not adequately justified
  - The research questions are too broad or unclear
5. Are the methods appropriate to the research question(s)?
  - The methods are fully adapted to each research question
  - Some of the methods are not adapted to some of the research questions
  - No link is made between the methods with the research questions

## Sampling and Data Collection

6. Is the sampling strategy well justified and appropriate? Is the sample sufficient?
  - The research justifies the sampling method and the sample
  - The sample is described without any real justification
  - No sample indicated

- 7. Are data collection procedures clearly described? Were tools tested? Where was data collected and why?
  - Data collection tools are all explained, validated and justified
  - Data collection tools are described but not justified or tested
  - Data collection tools are not fully explained
- 8. Are the roles of researchers clearly described? Are the researchers' skills, motives, position in terms of power relation (gender, ethnicity, age, employment) described and discussed?
  - The role of the researcher is explained and contemplated
  - The role of the researcher is explained but not adequately contemplated
  - No description of the role of the researcher
- 9. Are ethical issues in data collection addressed (processes for consent, maintaining confidentiality, etc.)?
  - All ethical procedures are explained (Review Board, information, consent form, confidentiality, voluntary participation)
  - Ethical processes are partially described
  - No mention of ethical reflection and necessary adaptation

## • Analysis •••••

- 10. Is the data analysis explicit? Use of raw data? Analytical framework? Are responses compared to other groups?
  - The analytical framework and analysis plan (method) are fully described
  - The analysis plan is described but sections are vague
  - No description of the analysis plan
- 11. Is the data analysis reliable? Did more than one person code/analyse the data? Was interpretation compared between coders?
  - The researcher explains how methods used are likely to ensure reliability
  - Reliability is mentioned but without any mention of the method
  - No mention of reliability
- 12. Is data triangulated to avoid researcher bias? Is there a validation procedure?
  - Several methods are applied to check the validity of data
  - A limited number of methods are used for triangulation
  - No mention of triangulation



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