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REVIEW ARTICLE

Orofacial clefts in low and middle-income countries: A scoping review of quality and quantity of research based on literature between 2010-2019

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Author Contributions

Study design: ES, PM. Data collection: ES, AS. Data analysis: ES, PM. Manuscript preparation: ES, AS, PM.

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Introduction

The Sustainable Development Goals (SDGs), consists of 17 goals, and are designed by global community to ensure well-being for all.¹ SDGs underlined the importance to reinforced health systems by improving health service capacity and maintain sustainability. The United Nations and World Health Organization (WHO) expect that low and middle-income countries (LMIC) around the world will strive to achieve the SDGs within the next decade.² In addition, WHO strongly encourages that all UN countries to accomplish Universal Health Coverage (UHC) in which all people are able to access quality health care as necessary without financial burden.³ However, birth defects such as orofacial clefts (OFC), cause significant challenges both in terms of treatment and prevention. In supporting the global health agendas, various types of non-governmental philanthropic funding have invested in many programs, one of which is the OFC management in LMIC.

Orofacial clefts (OFC) are the most common forms of craniofacial birth defects with a collective birth prevalence of 1.5 per 1,000 births. Not only OFC birth prevalence, but also surveillance systems, access to healthcare, quality of healthcare, and infant mortality appears to vary according to geographical area.⁴

OFC has attracted the attention of many researchers, exhibited by abundant number of publications in the indexed literature in various themes ranging from genetic, clinical, to socio-economic studies. Specifically, in LMIC, where OFC management is limited in terms of capacity and resources, overview of OFC research has never been reported before. This is crucial to evaluate the research gaps, identify key areas for collaborations and inform public health issues which may support OFC prevention and management. The objectives of this study are to:

- (a) scan the current literature to describe both quantity and quality of research activity in the field of OFC in LMIC

- (b) to highlight inequalities in the geographical spread of publications and information dissemination
- (c) to underpin a strategy for capacity building opportunities for partners that have limited research capacity to analyse their data and to publish and
- (d) to identify gaps in the literature that may help set the public health agenda for achieving the SDGs and particularly UHC with respect to OFC in low to middle income countries (LMIC).

Materials and methods

This study was performed following published scoping review protocol by Arksey and O'Malley (2005) and reporting protocol by Preferred Reporting Items for Systematic Reviews and Meta-Analysis.^{5,6} A search strategy was established to ascertain OFC studies in LMIC. Due to focus on trends and pattern of OFC in LMIC, the search result was limited to the last decade of publication (2010-2019). ES and PAM built the research questions and the coding plan. The World Bank provided the list of 138 LMIC countries.⁷ The initial protocol decided a set of key words. MeSH terms were used when available. Two database search engines (PubMed and Cochrane Library) were used to search these key words in May 2020. Google Scholar search was conducted to retrieve records which were not found on PubMed and Cochrane Library. Furthermore, reference lists of structured review articles were examined to identify papers that were not captured in the previous pathway. Inclusion and exclusion criteria were discussed and agreed to ensure consistency in the choice of articles (Table 1). The search strategy yielded 1,252 articles from three search engines. The detailed literature search protocol was explained in PRISMA flow chart (Figure 1).

Initially, 713 articles were exported to a reference manager (Mendeley™). Two authors (ES and AS) screened the title and abstracts of the articles independently to exclude duplicates using on the inclusion-exclusion criteria to exclude articles not relevant to our study aims and objectives. This process was performed simultaneously with data extraction into a specified Excel spreadsheet following the coding scheme (authors, years of publication, geographical settings and regions, type of studies, project themes and exclusion reasons). The classification of region used in this study was derived from United Nations Statistics Division.⁸ Type of publications were divided into 3 categories: empiric (qualitative and or quantitative), structured review (systematic or meta-analysis), and non-structured review. The publication

themes were grouped into 19 categories. Final decisions were taken by consensus. Full-text screening was pursued whenever necessary information was not available in the abstracts. The spreadsheet was transferred to IBM SPSS Statistics for Windows version 25 for descriptive quantitative analysis (IBM Corp., Armonk, N.Y., USA).

Results

After comprehensive screening and coding, 620 articles were included in this study. Overall, the number of publications on OFC in LMIC was fluctuated over the last decade (Figure 2). The number of publications between the first half of the decade (2010-2014) and the second half of the decade (2015-2019) was equal with 310 papers for each half decade. The number of publications was constant between 2010-2011 and spiked in 2012 where it remained stagnant until 2015. The number then dropped until 2017 and increased again until 2019. The total publications in 2019 was still lower than the highest number of publications in 2015.

It was felt that our scoping review ought to differentiate the different types of publication, the areas or subjects in the OFC field that were deemed to be of interest in different LMIC and the global geographic distribution. Characteristics of the included studies were tabulated based on the type of publications, project themes / subject matter, as well as countries and regions of settings (Table 2). The included articles were subdivided into three categories due to the different research approach: empiric studies (quantitative and qualitative), non-structured reviews, and structured reviews. Empirical studies dominated the type of publications (93.4%). Less than 7% of articles served as non-structured reviews and structured reviews papers, 4.2% and 2.4% respectively. The structured reviews were drawn from prevalence, service assessment, and genetic studies (n=6/5/4). As per geographic distribution, the number of publications from Asia led the indexed literature (n=349), followed by Americas, Africa, Europe, and Oceania. Only 53 countries out of 138 LMIC were represented among the 620 OFC publications. Asia led the number of countries which served as the settings of indexed literature in this scoping review followed by Africa, America, Europe, and Oceania (n=21/18/10/3/1). Oceania was presented by Marshall Island with 1 publication. In Europe LMIC contributors were Georgia, Romania and Serbia. One fifth of the publications were produced in China (21.5%). Brazil (13.1%) was number one among the Americas LMIC.

In terms of topics, genetics was the most pursued research theme on OFC in LMIC settings (19.8%), and between 62-97 publications were developed from the themes of prevalence,

surgical repair, risk factor, and service assessment studies. Of the others presurgical infant orthopedics, feeding, orthodontic, and foetal studies were among the least discussed topics in OFC. Seventeen LMIC only produced 1 OFC publication in the last decade.

In Asia and Americas, OFC genetic studies taken the largest proportion among other project themes (Figure 3). Whereas in Africa, number of publications in prevalence and surgical repair themes were comparable. The most discussed OFC issues in cross-regional studies were service assessment. Six OFC project themes were published in Europe being 2 were risk factor studies and the rest themes only 1 publication each. Only one publication of OFC in Oceania region in the last decade and it was a risk-factor study.

The proportion of project themes in the top 10 contributor countries (multi-settings excluded) were illustrated (Figure 4). Genetic studies derived from China samples (n=65) contributed more than the rest LMIC did altogether. Risk-factor and prevalence studies also played major role in China (n=20/11). Brazilian studies predominantly generated from genetic and intra oral evaluation studies, 20 and 14 publications, respectively. The 3 most popular OFC themes in India were surgical repair, prevalence, and service assessment studies (n=15/9/8). Specifically, for prevalence studies, Iran exceeded China in the number of publications (n=14/11). Both Thailand and China lead LMIC in speech, language and hearing studies (n=9 each). Thailand was also a key player in service assessment studies at 10 papers, the highest among other LMIC.

There were 37 multi-national collaboration studies in which 24 of them were cross-regional, 8 were intra-Africa, 2 were intra-Americas, and 3 were intra-Asia settings. The majority of the multi-countries publication discussed service assessment, genetic, and prevalence (n=9/7/5).

Discussion

Study limitations

This scoping review provides overview of OFC publications in LMIC, limited to trends in project themes and geographical settings through a systematic search process, rather than a full-inventory of the methodology and findings of all included studies. Given the volume of the final selected articles, this study did not pursue grey literature search. Although this review targeted to map the entire indexed literature on OFC in LMIC, it is possible that some studies were not detected. Therefore, the methodology in this study utilized comprehensive databases as well as screening of the bibliographies of the structured reviews.

LMIC versus the world

According to the World Bank Data, in 2018, birth rate per 1,000 births in high-income countries versus LMIC were 10.312 and 19.666. Moreover, in 2018, infant mortality rate per 1,000 live births in high-income countries versus LMIC per 1,000 births were 4.3 versus 31.309.⁹ The most frequent cause of infant mortality is birth defects.¹⁰ Furthermore, OFC is the most frequently occurring craniofacial defect.⁴ These inequalities between high-income countries and LMIC are also seen in the quantity of OFC peer-reviewed publications.

When the same set of keywords without any LMIC implications were applied at the search strategy in PubMed during the same time period (2010-2019), the result yielded 7,919 records. The current scoping review filtered LMIC-only settings which gathered only 620 articles. Meaning, there were approximately 7,300 publications in the indexed literature which utilised non-LMIC as the settings. Assuming that this number were overestimated, there is a massive discrepancy between OFC published research in LMIC versus non-LMIC settings.

Multi-settings studies

There were 37 papers involving several nations as the settings, in which 24 of those were cross regionals. These research activities were enabled by international collaborations between researchers or supported by international humanitarian bodies as the data provider. These facts highlighted the pivotal role of non-governmental organisations (NGOs) and humanitarian bodies in LMIC, not only do they alleviate the surgical loads, but also encourage multi-nation collaborative OFC research through access of their database.

LMIC-focused studies

Seven of the selected papers in this scoping review utilized the word “LMIC” in the article title or abstract or in the keywords.^{11, 12, 13, 14, 15, 16, 17} In 2016, Kadir et al conducted a systematic review and meta-analysis of 31,475,278 births from 12 LMIC. This study found that 1 in every 730 babies is born with OFC.¹¹ Carlson et al (2016a) collected data of age during primary palatal repair in 11 LMIC in which the median age was ranged from 13.35-66.41 months.¹² There is a direct correlation between delayed access to primary cleft palate surgery and low national income status in LMIC.¹² Higashi et al (2015) analysed Global Burden of Disease 2012 Study. Burden of disease caused by OFC can be lowered substantially by increasing access to surgical repair in LMIC.¹³ Carlson et al (2016b) gathered Operation Smile surgical data in 12 LMIC and country income indicators from WHO and

World Bank. Although positioned in the same income categories, different LMIC countries have varied OFC surgical backlog. This may indicate which countries should be prioritised in cleft care mission.¹⁴ Patel et al (2012) published a review paper focusing on cleft care delivery model in LMIC. This study highlighted 2 main issues (a) that there are still tremendous inequalities in the publication of data on all aspects of OFC and (b) OFC humanitarian missions play a vital role in increasing surgical capacity and promoting quality of care in LMIC health care system.¹⁵ Also, some NGOs such as Smile Train are renowned for the quality of the data they collect in the course of their missions to LMIC and these data could be used to good effect. An empirical study by Jenny et al (2017) incorporating Smile Train data in several LMIC countries observed substantial increase in surgical capacity of LMIC countries.¹⁶ A three-year survey study conducted by Massenburg et al (2016) facilitated by Smile Train in intercontinental LMIC settings concluded that according to the health care providers, major barriers to care for OFC patients were sourced from two aspects: patient aspect and health care provider aspect. The patient aspect is composed of lack of patient awareness, lack of financial support, patients travel cost, and poor patient health. The health care provider aspect consisted of lack of equipment, lack of available staff and lack of staff training.¹⁷ Smile Train also enabled the estimation of OFC-related infant mortality to be recorded in India.¹⁸ These studies corroborated the vital role of Smile Train not only in building surgical capacity by enhancing access to and training of local surgeons to do cleft repairs, but also they play a major role as a research stakeholder.

Surgery and anesthesia services have been adopted as the main component in UHC.¹⁹ Meara et al discussed in depth how surgery contributes to health, welfare and economic growth in LMIC.²⁰ Evidently, only 6% of total number of surgical interventions worldwide occurs in LMIC where over third of world population resides. Expansion of international support in cleft lip and palate repair is highly recommended. However, the existing support of cleft lip and palate repair is focused more on short-term surgical assistance and less long-term capacity building including preventive efforts.²⁰

Future research

It is postulated that the incidence of OFC is higher in LMIC than in non-LMIC. In addition, LMIC comprised of densely populated countries with higher birth rate which may indicate higher occurrence of OFC in LMIC. Although the figures of OFC incidence in LMIC was reported through a comprehensive meta-analysis in 2017,¹¹ this may not be the true due to problems with ascertainment. On the other side, the figure of OFC published research set in

non-LMIC was much greater than the number from LMIC. Tackling OFC is not an easy task, especially in LMIC which vary widely in the levels of healthcare infrastructure, capacity and other factors particular to each country. However research and public health data are deemed to be very important tools in empowering governments to identify and prioritise the issues and help formulate the solutions.

There is clearly still an issue of unmet need in the LMIC, a discrepancy needs to be addressed by increasing partnership between LMIC and non-LMIC researchers, including with the international funding bodies. Population based studies are recommended for resource-limited settings such as LMIC. **Error! Reference source not found.** This paper also recommends some OFC project themes which were less examined in different LMIC settings. This information will help inform governments, NGOs and humanitarian bodies to identify which LMIC require support in research and publication to help OFC prevention and management. Moreover, this study provides the evidence that LMIC governments can utilise to make greater commitment to OFC research and in turn support their country specific efforts to address the SDGs agenda and achieve UHC. We also propose that on the basis of these data OFC might be regarded as a sentinel condition that alerts LMIC to the broader issue of access to and availability of surgical care in general, and the stark inequalities that exist.

Conclusion

This scoping review provides general overview of research trends on OFC in LMIC. Over the last decade, the quantity of OFC publication in LMIC has fluctuated between 50 and 61 articles per year. Some LMIC had substantial published research in OFC while some were lacking. China, Brazil, and India remained the top source of OFC publication among other LMIC. Likewise, some OFC research themes were more explained than the others. The top three most discussed topics were genetics, prevalence, and surgical repair. The contribution of this paper highlights the need of capacity building in research in LMIC and offers recommendation for researchers, research grant funders, governments and humanitarian bodies to identify gaps in research and services, supporting LMIC in achieving Sustainable Development Goals 2030. Finally, this scoping review also highlights the problems with both capacity and capability in OFC research and publication. These data and the inequalities they highlight are key areas that require urgent attention in LMIC and following on from the lifesaving support from NGOs for surgical care and more recently multidisciplinary care and capacity building, the need for support for research data and publication is now paramount.

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This study was funded by Universitas Padjadjaran (1733/UN6.3.1/LT/2020 <https://www.unpad.ac.id/> to ES) and was performed under the guidance of the WHO Collaborating Centre for Oral Health and Craniofacial Anomalies at the School of Dentistry University of Dundee. The funder had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Author Contributions

Study design: ES, PM. Data collection: ES, AS. Data analysis: ES, PM. Manuscript preparation: ES, AS, PM.

Conflict of Interest

The authors declare no conflict of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Search terms

((cleft lip) OR (cleft palate) OR (orofacial cleft)) AND ((LMIC) OR (Afghanistan) OR (Albania) OR (Algeria) OR (American Samoa) OR (Angola) OR (Argentina) OR (Armenia) OR (Azerbaijan) OR (Bangladesh) OR (Belarus) OR (Belize) OR (Benin) OR (Bhutan) OR (Bolivia) OR (Bosnia and Herzegovina) OR (Botswana) OR (Brazil) OR (Bulgaria) OR (Burkina Faso) OR (Burundi) OR (Cabo Verde) OR (Cambodia) OR (Cameroon) OR (Central African Republic) OR (Chad) OR (China) OR (Colombia) OR (Comoros) OR (Congo) OR (Costa Rica) OR (Cote d'Ivoire) OR (Cuba) OR (Djibouti) OR (Dominica) OR (Dominican Republic) OR (Ecuador) OR (Egypt) OR (El Salvador) OR (Equatorial Guinea) OR (Eritrea) OR (Eswatini) OR (Ethiopia) OR (Fiji) OR (Gabon) OR (Gambia) OR (Georgia) OR (Ghana) OR (Grenada) OR (Guatemala) OR (Guinea) OR (Guinea-Bissau) OR (Guyana) OR (Haiti) OR (Honduras) OR (India) OR (Indonesia) OR (Iran) OR (Iraq) OR (Jamaica) OR (Jordan) OR (Kazakhstan) OR (Kenya) OR (Kiribati) OR (Korea) OR (Kosovo) OR (Kyrgyz Republic) OR (Lao PDR) OR (Lebanon) OR (Lesotho) OR (Liberia) OR (Libya) OR (Madagascar) OR (Malawi) OR (Malaysia) OR (Maldives) OR (Mali) OR (Marshall Islands) OR (Mauritania) OR (Mauritius) OR (Mexico) OR (Micronesia) OR (Moldova) OR (Mongolia) OR (Montenegro) OR (Morocco) OR (Mozambique) OR (Myanmar) OR (Namibia) OR (Nauru) OR (Nepal) OR (Nicaragua) OR (Niger) OR (Nigeria) OR (North Macedonia) OR (Pakistan) OR (Papua New Guinea) OR (Paraguay) OR (Peru) OR (Philippines) OR (Romania) OR (Russian Federation) OR (Rwanda) OR (Samoa) OR (Sao Tome and Principe) OR (Senegal) OR (Serbia) OR (Sierra Leone) OR (Solomon Islands) OR (Somalia) OR (South Africa) OR (South Sudan) OR (Sri Lanka) OR (St. Lucia) OR (St. Vincent and the Grenadines) OR (Sudan) OR (Suriname) OR (Syrian Arab Republic) OR (Tajikistan) OR (Tanzania) OR (Thailand) OR (Timor -Leste) OR (Togo) OR (Tonga) OR (Tunisia) OR (Turkey) OR (Turkmenistan) OR (Tuvalu) OR (Uganda) OR (Ukraine) OR (Uzbekistan) OR (Vanuatu) OR (Venezuela) OR (Vietnam) OR (West Bank and Gaza) OR (Yemen) OR (Zambia) OR (Zimbabwe))

Inclusion criteria

- Studies of OFC in low- and middle-income countries
- Empirical studies, structured review, or non-structured review including case report

Exclusion criteria

- non-English abstract
 - editorials, letters, short commentaries, news items, non-retrievable abstract
 - animal studies
 - non-OFC specific studies
 - cross-regional settings without focus in LMIC
-

Characteristics	Frequency	Percent	Characteristic	Frequency	Percent
Type of publications (# publications)			Country (# publications)		
Empiric	579	93.4	China	133	21.5
Non-structured review	26	4.2	Brazil	81	13.1
Structured review	15	2.4	India	72	11.6
Total	620	100.0	Multi-countries	37	6
			Thailand	37	6
			Nigeria	34	5.5
			Iran	32	5.2
			Mexico	20	3.2
			Colombia	12	1.9
			Malaysia	12	1.9
Project themes (# publications)			Vietnam	11	1.8
Genetic	123	19.8	Argentina	10	1.6
Prevalence	97	15.6	Pakistan	10	1.6
Surgical repair	76	12.3	Uganda	8	1.3
Risk-factor	62	10.0	Ethiopia	7	1.1
Service assessment	62	10	Lao PDR	7	1.1
Speech. language. and hearing	35	5.6	Peru	7	1.1
Intra oral evaluation	35	5.6	Turkey	7	1.1
Extra oral evaluation	23	3.7	Ecuador	6	1
Psychosocial	18	2.9	Egypt	6	1
Socioeconomic	16	2.6	South Africa	6	1
Quality of Life	16	2.6	Indonesia	5	0.8
Information technology	13	2.1	Nepal	5	0.8
Satisfaction	9	1.5	Tanzania	5	0.8
General health	8	1.3	Honduras	4	0.6
Syndrome (case report)	7	1.1	Zimbabwe	4	0.6
Presurgical Infant Orthopedics	7	1.1	Congo DR	3	0.5
Feeding	6	1.0	Georgia	3	0.5
Orthodontic	5	0.8	West Bank and Gaza	3	0.5
Fetal study	2	0.3	Burkina Faso	2	0.3
Total	620	100.0	Dominican Republic	2	0.3
			Ghana	2	0.3
			Kenya	2	0.3
			Madagascar	2	0.3
			Mongolia	2	0.3
			Romania	2	0.3
Regions (# publications)			Yemen	2	0.3
Asia	349	56.3			

Americas	146	23.5	Bangladesh	1	0.2
Africa	94	15.2	Benin	1	0.2
Cross-regional	24	3.9	Cambodia	1	0.2
Europe	6	1.0	Cote d'Ivoire	1	0.2
Oceania	1	0.2	Gabon	1	0.2
Total	620	100.0	Guatemala	1	0.2
			Iraq	1	0.2
			Jordan	1	0.2
			Mali	1	0.2
			Marshall Islands	1	0.2
			Nicaragua	1	0.2
Regions (# countries)			Rwanda	1	0.2
Asia	21	39.6	Serbia	1	0.2
Africa	18	34.0	Sri Lanka	1	0.2
Americas	10	18.9	Sudan	1	0.2
Europe	3	5.7	Syria	1	0.2
Oceania	1	1.9	Uzbekistan	1	0.2
Total	53	100.0	Total	620	100

publications