International Journal of Health Sciences and Research
www.ijhsr.org ISSN: 2249-9571

Original Research Article

Exploring R&D and Public Private Partnerships (PPPs) Initiatives on Leishmaniasis (Kala Azar) in India

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Received: 02/07/2016 *Revised: 20/07/2016* *Accepted: 22/07/2016*

ABSTRACT

Kala-azar (Visceral Leishmaniasis) continues to constitute huge public health problems and hurdle towards the socioeconomic development in India. The disease is endemic in more than 88 countries with approximately 350 million people at risk of infection and an estimated 1.3 million new cases annually. Kala azar is more prevalent in three countries of WHO SEA Region - Bangladesh, India and Nepal. India alone accounts for 50% of the global burden of kala azar and State Bihar alone captured almost 50% out of total burden in the Indian subcontinents. It affects the poorest folks on the planet, and is associated with malnutrition, poor housing, population movement, weak immune system and resource deficiency but considerably less attention has been paid on research and development (R&D) of new drugs and vaccine for this infectious disease. In order to overcome the challenges associated with Kala azar, it becomes critical to map the current landscape of R&D by examining patenting activity, ongoing clinical trials, evaluating R&D interest of public and private sector and exploring the emerging public private partnerships (PPPs) initiatives on Kala azar in India. In this regard, the data reveals that only few industries and government research institutions are engaged in R&D efforts. The collaborative PPPs approach regarded as a useful solution to accelerate R&D and could delivers the affordable innovative health solutions by compensating for drug development and market failure by reducing cost and risk sharing.

Keywords: Visceral Leishmaniasis, Neglected Diseases, Research and Development, Public private partnership.

INTRODUCTION

Kala-azar (visceral leishmaniasis) is a disastrous neglected disease (NDs) and second largest parasitic killer in the world after Malaria [1] caused by a protozoan parasite *Leishmania donovani* and spread by sandfly (Phlebotomineargentipes).This is one of the most diverse and complex form of vector borne diseases as it involves several overlapping species and sand fly vectors, the disease has a complex ecology and epidemiology. More than 90 sandfly species are known to transmit Leishmania parasites. [2] The term "Kala azar" is also known as black fever, Indian leishmaniasis, visceral leishmaniasis (VL), leishmania infection, dumdum fever and black sickness. In Indian sub-continent, it is transmitted from human to vector to human and generally the patients with VL have symptoms like fever, cough, abdominal pain and diarrhea. [3] The disease rapidly become fatal and attacks on the internal organs. [4] In the endemic districts, Kala azar affects the poorest with little knowledge about the disease and limited access to diagnosis and treatment. The expensive health expenditure and financial losses pushes them in the cycle of poverty. [5] The tale of the Kala azar was began from 1862 and 1872, where it

was identified as "Burdwan Fever" reported in west Bengal. The initial case was also confused with malaria but in 1903 the parasite was identified as *Leishmania donovani*. In 1882, the first case of kala azar was identified in Bihar and then most of the cases were reported from Bihar and other states like Assam, Bengal, Uttar Pradesh and Tamil Nadu. In the end of 1950s, the spates of kala azar were thought to be over by spraying of dichlorodiphenyltrichloroethane (DDT) under national malaria eradication program (NMEP) and stopped in 1964 after accepting that the disease had been eradicated, but the VL has recurred in Bihar in 1970 with high morbidity and mortality and then again spray of DDT was done from 1977 to 1980 and discontinued. Again in 1992 and 1995 kala azar cases pushes with increased number of incidence [6] and then DDT measured as a temporary solution. In order to eradicate leishmaniasis, the Government of India (GoI) has taken several measures e.g. kala azar control program (1991) in which the spray session was started again and discontinued in 1995, the effect was continued up to 2001. In 2002, removal of kala azar was included in national health policy with the aim of "elimination of kala azar by 2010" and it was revised to 2015. [7] The policy included three main activities, such as control of vector population by spraying DDT, early diagnosis & treatment and health education to promote awareness and protective actions to avoid risk of disease. [8] In 2005 the "Kala Azar Control Program" was included in "National Rural Health Mission" and named as "National Vector Borne Disease Control Program" (Table 2).

Table 1: Leishmaniasis: Global and Indian Epidemics Fact Sheet

Visceral Leishmaniasis	India VL fact sheet	Cutaneous Leishmaniasis	Population at risk
2 lakh - 4 lakh Estimated incidence of VL and over 20 000 deaths annually. More than 90% cases of VL are reported from India, Bangladesh, Brazil, Ethiopia, South Sudan, and Sudan.	Endemic in **52 districts of Bihar**, Uttar Pradesh, Jharkhand and West Bengal. Bihar constitutes almost 50% of total burden in the Indian subcontinent. Loss of about 400,000 disability adjusted life years (DALYs) every year in this region.	**0.7-1.3 million** Cases of cutaneous leishmaniasis (CL) reported in the last 5 years. More than 95% of CL cases are reported in Americas, the Mediterranean basin, and the Middle East and Central Asia. Over 2/3rd new cases found in; Afghanistan, Algeria, Brazil, Colombia, Iran (Islamic Republic of) and the Syrian Arab Republic.	**310 million** People are at risk of infection in six countries reporting over 90% VL cases worldwide.
Source: Adapted from Leishmaniasis. Fact sheet N°375. World Health Organisations (WHO) [Internet]. 2014 [updated 2016 March; cited 2016 May]. Available from http://www.who.int/mediacentre/factsheets/fs375/en/ Sharma U, Singh S. Insect vectors of leishmania: distribution, physiology and their control. J Vector Borne Dis. 2008; 45: 255–272. Muniaraj M. The lost hope of elimination of Kala azar (visceral leishmaniasis) by 2010 and cyclic occurrence of its outbreak in India, blame falls on vector control practices or coinfection with human immunodeficiency virus or therapeutic modalities. Tropical Parasitology. 2014; 4 (1). Research and development for neglected diseases. ICMR bulletin. 2006; 36:1-3.			

Table 2: Initiatives to Eradicate Visceral leishmaniasis (kala azar) in India

1960:	Control measure adapted under the National Malaria Eradication Program (NMEP). The Government of India (GoI) launched a centrally sponsored "Kala azar Control Program".
1991:	Program reviewed by an expert committee chaired by the director General of health services & recommended to include in the National Health Policy.
2000:	Accordingly it was included in the National Health Policy 2002 which set a goal for the elimination of Kala‑azar by 2010, which was revised to 2015.
2002:	The "Kala‑azar control program" was then merged with "National Rural Health Mission" under the name of "National Vector Borne Diseases Control Program".
2005:	
Source: Muniaraj M. The lost hope of elimination of Kala azar (visceral leishmaniasis) by 2010 and cyclic occurrence of its outbreak in India, blame falls on vector control practices or coinfection with human immunodeficiency virus or therapeutic modalities. Tropical Parasitology. 2014; 4 (1). How did it get so bad? Down to earth [Internet]. 1999 [updated 1999 Apr.; cited 2016 May]. Available from http://www.downtoearth.org.in/coverage/how-did-it-get-so-bad-19701	

The diagnosis of the disease was very difficult because of other common occurring diseases such as malaria, typhoid, and tuberculosis share similar symptoms; present along as co infection, but there are methods for diagnoses [9] such as, direct observation of the parasites but culturing parasites is expensive and time consuming process, requires expertise and costly equipment, quite painful, severely restricting its use in routine clinical practice. Although several serological diagnostic tests have been developed, but none is in practice because of drawbacks like high cost, need for electricity, complex technical procedures and inadequate specificity and sensitivity [10] and the treatment options for visceral leishmaniasis (VL) are inadequate and unsatisfactory, [11] the treatment options are mostly dependent on chemotherapy. Pentavalent antimonials, oral miltefosine, amphotericin B, liposomal amphotericin B and paromomycin are most commonly used drugs, but these drugs are associated with complications e.g. cost, toxicity, route of injection, long duration of treatment and drug resistance. [12] The approach of combinational drugs was also developed which shows excellent cure rates. They must be used with care given to the possibility that, if not applied in a controlled and regulated way, resistance could be induced in leishmania parasite leads to loss of efficacy of two therapeutic options [7] (Table 3). Although some studies in mouse model also shows that the *L. donovani* can develop resistance to drugs, even when they are used in combination. [13] Therefore, to achieve long-term goals of controlling and eliminating this disease, there is an urgent need for an effective vaccine. [12] According to the report by global health progress, the primary drivers of vaccine R&D for NDs are public private interaction for product development. [14] The WHO road map 2020, the London Declaration in 2012 and World Health Assembly Resolution in 2013 provide opportunities to accelerate the activities towards reducing the impact of NDs including VL and emphasised the need for a comprehensive approach or effective partnerships. [14,15] The aim of the study is to map the current landscape of R&D and emerging public private initiatives for kala azar in India through assessment of the patenting activity, ongoing clinical trials and technology transfer, R&D interest area of the public and private sectors and number of active performers involved in research on VL.

Table 3: Drugs available for the treatment of Leishmaniasis & their status

Drug	Status	Details
Sodium Stibogluconate (Sbv)	Resistant (Decreased Efficacy)	The success rate was fell down to 36% in 1996 & in 2001 the success rate was 35% & suggested to be abandon.
Pentamidine	Resistant (Decreased Efficacy & Increase Toxicity)	In early 1990s, its efficacy had dwindled & the success rate had decreased, ultimately abandoned in 2003.
Amphotericin B	Cure Rate Decline, Resistant Developed in some areas.	Reports showed a declining success rate & development of resistance in a patient from Lucknow, UP in 2011.
Miltefosine (first oral drug) 2002	Cure Rate Decline, Decreased Efficacy	In 2010, death due to VL once again increased and the success rate of miltefosine also declined.
Paromomycin	Shown to be safe and effective in a phase III clinical trial in India, with a final success rate of 94.6%, phase IV study was conducted recently showed the final cure rate of 94.2%.	Registered for the treatment of VL in India in 2006 and was included in the WHO Essential Medicines List and WHO Essential Medicine for Children.
Combination Drug		
Liposomal Amphotericin B with Miltefosine		97.5% Success Rate
Liposomal Amphotericin B with Paromomycin		97.5% Success Rate
Miltefosine with Paromomycin		98.7% Success Rate
Source: Adapted from Muniaraj M. 2014.		

METHODOLOGY

Present study has attempted to identify the public sector R&D laboratories and industry organizations working in leishmaniasis and health innovation related activities in India. The data in this regard

was accessed from the database of Controller General of Patent Design and Trademarks (CGPDTM), Clinical Trial Registry India (CTRI) and other government organisations websites, journal articles, annual reports, World Health Organization reports and press releases obtained from the websites of public organisations and industries.

RESULTS AND DISCUSSION

Analysis of Patents granted on Leishmaniasis (Kala azar) in India

Total eight pharmaceutical patents were granted for leishmaniasis in India which clearly depicts that the condition of R&D for NDs specifically for kala azar. The analyses of nature of patents shows that the pharmaceuticals R&D activities are still inclined towards the process, composition, combination and new form of substances and few for new drug delivery system (NDDS) and product patent (Table 4). Percentage share by performers of pharmaceutical granted patent are 75%, 12% and 13% for public research institutes, Institute of national importance (INI) and industry respectively. The public research institutes include government research organisation e.g. Council of scientific and industrial research (CSIR) shares, one of the important part of Pharma patents on leishmaniasis. Among the CSIR laboratories, only few laboratories including Central drug research institute (CDRI), Indian institute of chemical biology (IICB) and Centre for cellular and molecular biology (CCMB) are relatively more active in case of kala azar in India. IICB has been granted patent for complete soluble protein antigen as vaccine, developing VL detection candidates and process for the preparation of a Hybrid Cell Vaccine against leishmaniasis. IICB has done collaboration with London School of Hygiene UK and Tropical Medicine, MOLOGEN AG Germany, Charite Universitatsmedizin Germany, Institute Pasteur de Tunis Tunisia, Hebrew University of Jerusalem Israel, Rajendra Memorial Research Institute India, Drugs for Neglected Diseases Initiative Switzerland for the development of DNA vaccine for VL known as LEISHDNAVAX. [16] The preclinical studies found that the LEISHDNAVAX was safe in both naive and leishmaniasis infected mice, the results support the beginning of clinical trials for both preventive and therapeutic applications of the vaccine. [17] Various extramural research projects on leishmaniasis were also implemented (Table 5). These schemes shows how the pattern of collaboration for technology development is shaping up and emerge as an effective tool for attracting different sector for doing systematic work to achieve aim. CDRI has been granted patent for novel substituted benzocycloalkyl azole derivatives as antileishmanial agents. CDRI also developed two diagnostic test for leishmaniasis i.e. PCR-Based Diagnostic Probe and Direct Agglutination Test (DAT). CCMB was granted patent for the composition useful for the treatment of leishmaniasis in collaboration with Jawaharlal Nehru University. Other than CSIR labs, Bose institute and All India Institute of Medical Sciences are also working on kala azar. Indian council of medical research (ICMR) developed PCR based diagnosis, ELISA and other immunological tests for early detection of leishmaniasis. RMRI, Patna was identified as WHO reference centre for leishmania parasite and serum bank. [18] In case of private sector, Claris Life Sciences Ltd. has been granted patent for the process of preparing amphotericin-b liposome for injection. Analysis of patents reveals that very few industries and public sector institutions are engaged in R&D efforts in this area and also explained that public private partnership (PPPs) are playing relatively significant role to stimulate R&D and manage funding.

Table 4: Analysis of Pharmaceutical Patent Granted on Leishmaniasis in India

Nature of Patent	2009-2010	2011-2012	2013-2014	2015-2016	Total
Process patent	02	02			04
NDDS patent		01			01
Method of treatment Dosage, Formulation Composition, Combination, NCE Patent & Product Patent		01		01	02
New forms of substances				01	01
Grand total	**02**	**04**		**02**	**08**
Note: NDDS-New drug delivery system, NCE-New Chemical Entity. **Source**: Compiled by author, Data accessed from data base of Controller General of Patent Design and Trademarks (CGPDTM), Government of India (GOI) till 13 June 2016.					

Table 5: IICB Extramural R&D funded projects on leishmaniasis in India

Projects	Funding Agency	Cost
Phyllanthns amarns a novel source of antileishmanial drug	ICMR	28.5 lakh
Effect of the membrane proteins of attenuated Leishmania donovani on the growth of cancer cell	ICMR	6.48 lakh (first year installment)
Protective efficacy of purified constituents of Centella asiatica leaf extract in an experimental model of visceral leishmaniasis	DBT GAP 251	6.58 lakh (first year release 2007-08)
Cyclic nucleotide signaling in the infectivity of an eukaryotic intracellular pathogen like Leishmania	DST GAP 239	21.74 lakh
Lipid immunity to vaccine generation: Identification, protective efficacy and mechanism of action of Leishmanial Glycolipid in the Murine model of Visceral Leishmaniasis	DST GAP 264	19.75 lakh
A comparative evaluation of the potency and durability of leishmanial donovani gp63 DNA - and protein-based vaccines against experimental visceral leishmaniasis	DST GAP 260	23.23 lakh
New tools for monitoring drug resistance and treatment response in Visceral Leishmaniasis in the Indian subcontinent	EU GAP-270	Euro 288,000
Development of a DNA vaccine for visceral leishmaniasis	EU GAP-270	Euro 65,250
Source: Compiled by author, Data accessed from IICB website.		

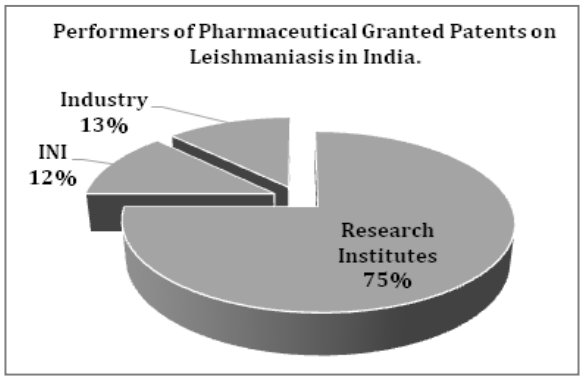

Figure 1: Percentage share by Performer of Pharmaceutical Granted Patent on Leishmaniasis in India.
Abbreviation: INI Institute of National Importance.
Source: Compiled by author, data accessed from data base of Controller General of Patent Design and Trademarks (CGPDTM), Government of India (GOI) till 13 June 2016.

Analysis of clinical trial on Leishmaniasis (Kala azar) in India

Data reveals that, only eleven clinical trials were going are being conducted by less number of industries, universities and research institutes namely Bharat Serums and Vaccines Ltd, School of Tropical Medicine Kolkata West Bengal, Kala azar Medical Research Centre, Institute of Medical Science (Banaras Hindu University), Rajendra Memorial Research Institute of Medical Science (RMRIMS), Father Muller Medical College Hospital, Mangalore (Table 6). In term of performer-wise clinical research data discloses that share of these entities is as follows: private sector or industries (9%) research institutes (73%), medical colleges, hospitals, and universities (18%). Maximum of clinical trials are related to study of single dose or two different doses or combination of available drugs (e.g. amphotericin B, miltefosine, paromomycin etc.), observational studies and short course of treatment but drug resistance is the major drawback in the medication of visceral leishmaniasis, thus now it essential to focus on the development of vaccine to stop its reoccurrence and complete eradication but none of the CT specifically deal with vaccine for kala azar. Table 6 defines the pattern of phase wise clinical R&D

activities on Leishmaniasis in India and shows different organisations e.g. Department of Science & Technology (DST), Drugs for Neglected Diseases initiative (DNDi), Medecins Sans Frontieres (MSF) etc. collaborate to provide fund or material support to conduct CT in India.

Table 6: Pattern of Phase wise clinical R&D activities on Leishmaniasis in India

Principal Investigator	Phase of Clinical Trial	Type of Study	Monetary or Material Support	Sponsor
Bharat Serums and Vaccines Ltd	Phase III	Drug	Bharat Serums & Vaccines Limited	Bharat Serums & Vaccines Limited
Institute of Medical Sciences Banaras Hindu University Varanasi	Phase III	N/A	DNDi (Drugs for Neglected Diseases Initiative)	N/A
School of Tropical Medicine Kolkata West Bengal.	N/A	Short course treatment of kala-azar	Life care Innovations Pvt. Ltd.	Dr R P Goswami School of tropical Medicine Kolkata Life care Innovations Pvt Ltd
Rajendra Memorial Research Institute of Medical Sciences (RMRIMS)	N/A	N/A	Medecins Sans Frontieres (MSF)	Rajendra Memorial Research Institute of Medical Sciences (RMRIMS)
Rajendra Memorial Research Institute of Medical Sciences (RMRIMS)	Phase II / Phase III	N/A	Medecins Sans Frontieres (MSF)	N/A
Kala-Azar Medical Research Centre	Phase II	Drug	Department of Science & Technology (DST)	Life care Innovations Pvt Ltd & GVK Biosciences P Ltd
Rajendra Memorial Research Institute of Medical Sciences (RMRIMS)	Phase IV	Drug	Drugs for Neglected Diseases initiative (DNDi)	Drugs for Neglected Diseases initiative (DNDi)
Father Muller Medical College Hospital, Kankanady, Mangalore	Nil	Observational	MendoncaBryneSharel	MendoncaBryneSharel Father Muller Medical College Hospital
Rajendra Memorial Research Institute of Medical Sciences (RMRIMS)	Phase III	Drug	Medecins Sans Frontieres (MSF)	Medecins Sans Frontieres (MSF)
Rajendra Memorial Research Institute of Medical Sciences (RMRIMS)	N/A	Observational	Rajendra Memorial Research Institute of Medical Sciences (RMRIMS)	Rajendra Memorial Research Institute of Medical Sciences (RMRIMS)
Rajendra Memorial Research Institute of Medical Sciences (RMRIMS)	N/A	Drug	Rajendra Memorial Research Institute of Medical Sciences (RMRIMS)	Rajendra Memorial Research Institute of Medical Sciences (RMRIMS)
Source: Data collected from Clinical Trial Registry India (CTRI) database, till 11 June 2016.				

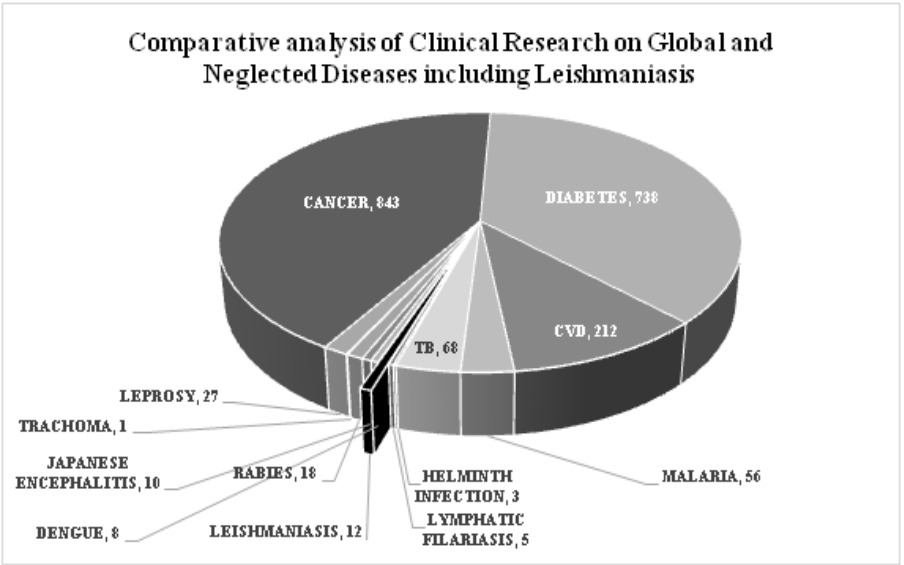

Figure 2: Comparative analysis of Clinical Research on Global and Neglected Diseases including Leishmaniasis.
Source: Compiled by Author, Data accessed from Clinical Trial Registry India (CTRI) Database till 13 June 2016.

Public Private Partnership (PPPs) initiatives on leishmaniasis in India

Working definition of a Partnership is "a relationship based upon agreements, reflecting mutual responsibilities in furtherance of shared interests." [19] Partners from private and public sectors in different combinations are working together to share financial and non-financial resources to develop urgently needed medicines and treatments to developing countries." [12] In 2013, Science Technology and Innovation Policy (STIP) also promoted the establishment of large R&D facilities in public private partnership mode (Public funds for partnerships with the private sector for social and public welfare) with provision for benefit sharing. The policy also focused on co sharing of Intellectual property rights (IPRs) generated under PPP and facilitating private sector investment in R&D centres in India and overseas. [20] The WHO roadmap 2020, inspired governments organisations, pharmaceuticals firms and nongovernmental organisations (NGO) to collaborate and control or eliminate ten devastating NDs in 2012 as London declaration, it includes lymphatic filariasis, soil transmitted helminthiasis (STH), trachoma, leprosy and VL. [21] RMRIMS and the Liverpool School of Tropical Medicine (LSTM) also collaborate (with funding $1,922,510) to develop a diagnostic test that allows real time detection of pesticide levels, thus allowing repeat spraying whenever required. For this, laboratory prototypes have been developed and in vivo optimisation is in process. [22] In 2012, AstraZeneca and DNDi began partnership for drug compound screening of NDs i.e. leishmaniasis, Chagas disease, and sleeping sickness, in which the industry contributed 15000 potential compound with DNDi for further screening with aim to work together and develop new therapeutic approach against these fatal diseases. [14] Other than these partnerships, New Millennium Indian Technology Leadership Initiative (NMITLI) of Council of Scientific & Industrial Research (CSIR), Drugs and Pharmaceuticals Research Program (DPRP) & Technology Development Board (TDB) of Department of Science & Technology (DST) and Small Business Innovation Research Initiative (SBIRI) of Department of Biotechnology (DBT) are also the representatives of PPPs, but only few were worked for NDs. In case of VL, DPRP funds Bharat Serum and Vaccine Ltd for conducting CT on kala azar in 2008 [23] and SBIRI funds Life Care Innovations Pvt. Ltd. for drug development. [24] Initiatives from private sector for leishmaniasis are very less, some of the successful public private interactions are observed in this section as Rapid Visual Immunochromatographic test for qualitative detection of anti-Leishmanial antibodies by using serum or plasma (Crystal-KA) developed by the All India Institute of Medical Sciences (AIIMS) and funded under the DBT scheme and further marketed by Span Diagnostics. The industry converted it into immunochromatographic strip-test that is rapid (10 minutes); field-friendly refrigeration and electricity are not required. Thus, it can be used in the remotest part of India and readable with naked eyes, available at an economical price of about Rs 60-70/test. The company has done clinical and field trials at AIIMS, National Centre for Diseases Control (NCDC) and other laboratories in Bihar with highest possible accuracy and reproducibility. Finally, findings were approved and rolled by government of India in its National Kala Azar Control Program. [25] Another successful example of PPPs is development of combination therapy (amphotericin B, paromomycin, and miltefosine) by consortium of DNDi with ICMR, RMRI, the Kala azar Medical Research Centre (KMRC), and GVK Bio at Muzaffarpur for the clinical study to assess various drug combinations therapy for leishmaniasis as the existing treatments of disease have serious side effects. The study was accomplished in 2010 and results have shown higher efficacy with ≥ 97.5% success rate. [26] Therefore, the Public Private Partnership (PPP) approach should be

considered as useful & innovative solution to accelerate R&D, particularly for NDs including VL. The approach can compensate for market failure by reducing cost and risk involved for both public and private sector partners. It could deliver the new health benefits with affordable cost and filled the medicines gap between wealthy and poor peoples of the nation.

CONCLUSION

India has the highest burden of VL, which disproportionally affects the poorest and most marginalised groups and locks people into a series of poverty and disease. Present study found that, very few government research institutes are engaged in the R&D for VL and Indian companies are clearly not targeting the diseases of poor people, as new drug R&Ds is apparent as an expensive process and the pharmaceutical companies are unwilling to invest in the absence of a viable market and prospects for recouping investments.In the system of health research and technology development, there are many bottlenecks in the efforts to eliminate NDs. For India to achieve its ambitious for completely eradication of VL, there is a need of disease specific PPPs program, which particularly focus on the development of vaccine and other innovative treatments and also include the objectives to ensure that communities have access to medicine, diagnosis, clean water, sanitation, vector control, state wise surveillance program, awareness sessions, regular training of medical staff, improved living conditions and stronger health systems in endemic areas. It is to be hoped that the findings and proposed collaborative method will lead to greater focus on eradication of VL from India.

ACKNOWLEDGMENTS

The author is thankful to Central University of Gujarat, Gandhinagar for infrastructural support and author is also supported by the fellowship from University Grant Commission (UGC), Government of India.

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How to cite this article: Bharti R. Exploring R&D and public private partnerships (PPPs) initiatives on leishmaniasis (kala azar) in India. Int J Health Sci Res. 2016; 6(8):259-267.

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