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Context, Content and Outcomes of Antimalarial Drug Policy in India: An Analysis and Perspective

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ABSTRACT

Objective: Analysis of Antimalarial Drug Policy in India. Subject/Method: Policy Analysis and Secondary Research Review. Findings: Drug list expanded extensively and the drug dose intensity is proportional to disease transmission in region/area; medicalizing the community significantly. The conceptual understanding of malaria remains within biomedicine domain evidenced by the fact that much of importance (over-reliance) given to least effective individual level technical interventions like drugs that too; without considering immunity and nutritional status of both individual and community. Indian planners seems confused to differentiate (or ignoring) between Malaria's behavior at individual level and community level. Thus, the Malaria planning lacks ethical consideration for resource allocation in Public Health Planning evidenced by the fact that large resources allocated to least effective intervention that serves the profit making purpose of private sector pharma industry. Sufferings of the most impoverished household of community remain unaddressed in health planning. Policy is unable to serve its primary purpose of relieving suffering of community, prevention of mortalities, reducing morbidities, slowing down the resistance, and reducing drug load in community. Conclusion: The investment in medications to tackle malaria as Public Health problem looks costly investments as it consumes heavy resources and its benefits/success claim is questionable. There is mismatch in planning and field reality as intervention in the form of drugs does not match the requirement as per epidemiological complexity. Health planning is comprehensive exercise for any country. Ignoring voices from field/frontline workers prove detrimental for health planning. Every organization or individual involved in health planning would be having different opinions as per their interest but the final decision regarding resource allocation should consider the field reality following good public health ethics.

Keywords: Malaria, Antimalarial drugs, Public health, Ethics

INTRODUCTION

The understanding of Malaria causation evolved from supernatural theory to Miasma theory to current germ theory [1]. It is considered as preventable and treatable in an individual if diagnosed and treated promptly and correctly [2,3]. It might re-emerge in favorable conditions (recrudescence) and may relapse at any point in time in the life of an individual once he/she is infected with parasite though cured of the disease and cleared parasitemia with the use of antimalarial medicine [1].

Antimalarial drugs are content of allopathic antimalarial pharmacotherapy. Every drug used as Antimalarial medicine has a specific action, mechanism of action (known/unknown), and associated adverse effects, and it may also have severe adverse events and complications associated with it [4].

The prerequisites to achieve maximum extent of success in the treatment of Malaria or Malaria case management (individual

level) are individual with better nutritional status, well-developed healthcare services system and unfavorable conditions for vector breeding and infection transmission. However, overall socioeconomic development is crucial in tackling malaria as a Public health problem in high or moderate transmission settings.

The cinchona policy in India remained "a political subject" between British Empire and Indian states. The quinine as treatment of physician choice practiced and established in India by practitioners of western medicine (without knowing exact antimalarial mechanism in human body and with possible severe adverse effects) [5]. The use of synthetic drugs CQ, AQ, PQ, and PYR (Chloroquine, Amodiaquine, Primaquine, and Pyrimethamine) to treat malaria was *de novo* following practices of colonialism during the late 1950s [6].

REVIEW STRATEGY/METHODOLOGY

The primary objective of this review is context-content-outcomes analysis of Antimalarial Drug Policy in India. The below mentioned steps followed to undertake this review research/policy analysis (Figure 1).

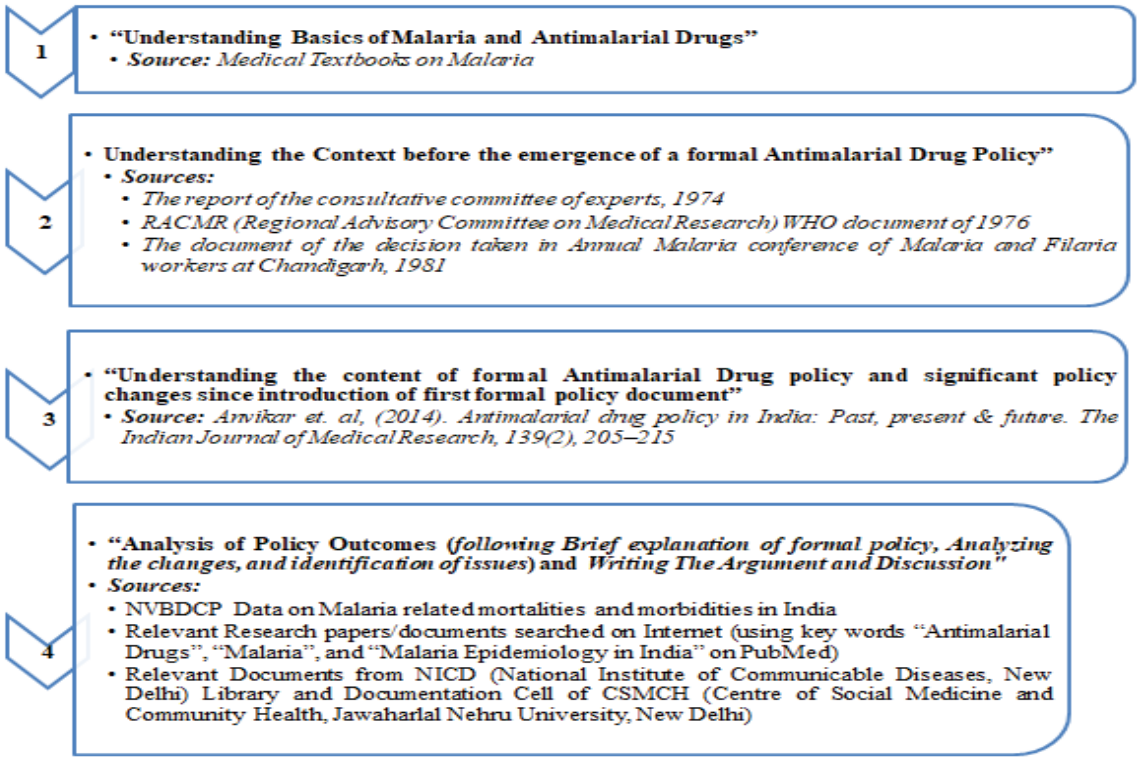

Figure 1. Schematic presentation of methodology of review/policy analysis

CONTEXT OF FORMAL ANTIMALARIAL DRUG POLICY

Various committees constituted by the government to review the program progress following the phenomenal success and large defeat of NMEP [7]. These revealed the limitations of eradication strategy of NMEP once the resurgence of malaria started along with changing dynamics and CQ resistance in *P. falciparum* reported by independent research studies in 1973.

The consultative committee of experts 1974, formed to determine the alternative strategies under the NMEP in resource constraint situation in the series of these review committees. The committee reviewed then existing situation and acknowledged the limitation of eradication strategy, the resurgence of malaria, urban malaria, and the problem of drug resistance and also mentioned the contribution of migration in the spread of drug-resistant strains with references to studies conducted in India. Despite resource constraints and expressing concern regarding availability, efficacy and limitations of antimalarial drugs by the committee itself, this committee recommended carrying out field research in order to find the most effective antimalarial drug and assessment of existing radical cure schedule [8].

WHO reviewed to identify priority areas of Malaria Research in South East Asia Region (Shifting from DDT Optimism to Antimalarial Drugs Optimism) and suggested the priority as "development of new drugs and field trials of drugs already available" [9]. On behalf of CSIR-CDRI assigned task for antimalarial drug development by ICMR under the MPO 1976 [10] meanwhile a

special *falciparum* containment program 1977 was also started in selected states under the objectives of MPO with the funding of SIDA/WHO [11]. MPO terminated later facing obvious failures [12].

In 1977, the first international malaria symposium organized by OPPI (Organization of Pharmaceutical Producers of India) in collaboration with ICMR (Indian Council of Medical Research). Dutta et al. presented a review of clinical trial (data from 1946 to 1974) in this symposium and expressed the opinion regarding the impossibility of malaria eradication from the world. Author/s emphasized to shift focus on preventing deaths by quoting the press report of WHO director-general Halfdan Mahler and International authorities also expressed views on limitations of antimalarial drugs and safety issues [10].

National Malaria and Filaria workers' conference held at Chandigarh from 25 to 27 April 1981, documented that *in vitro* evidence suggest shallow magnitude of the *falciparum* resistance in country. Further, it was advisable not to change the drug policy even in the districts of Northeastern states and few other states as in vitro evidence suggested [11]. Despite the need to remain extra cautious (critical planning) in resource allocation for health and healthcare in India after the realization of NMEP failure, discussions and policy processes went to draft formal Policy documents regarding Antimalarial drug usage in 1982, ignoring the voice of dissent. However, the work in the development of drug policy and drug research in India started gained pace and took shape under the influence of international organizations and patronage of private industries [10].

CONTENT OF FORMAL ANTIMALARIAL DRUG POLICY

First formal policy of antimalarial drugs introduced following the fear of increasing chloroquine resistance and *P. falciparum* related mortalities (despite non-availability of any authentic report regarding CQ sensitivity in vivax strain and non-availability of a single report regarding CQ sensitivity in *P. malarae*).

The areas labeled as resistant or sensitive according to data of sensitivity studies conducted at regional monitoring sites/sentinel sites and recommended different drug regimens for different areas.

The principal objective of policy was to slow down the spread of Chloroquine resistance until the finding of new safe and effective antimalarial drugs which can respond to chloroquine-resistant *P. falciparum* cases and the objective of Presumptive treatment was to prevent mortality in the absence of diagnostic facilities.

Table 1. First formal policy 1982; criteria for designating chloroquine resistance: areas with established CQ resistance by *in vivo* tests

Presumptive Treatment	Treatment after confirmation		Special Groups		
	***P. falciparum* Malaria**	***P. vivax* Malaria**	**Severe Malaria**	**Malaria in Pregnancy**	**Chemoprophylaxis or MDA**
CQ (10 mg/kg SD) in ACD, DDCs, and FTDs	CQ (10 mg/kg SD)+PQ (0.75 mg/kg SD)	CQ (10 mg/kg SD)+PQ (0.25 mg/kg for 5 days)	Parenteral CQ or Quinine	Contraindications: PQ	MDA in migrants: CQ (10 mg/kg)+PQ (0.75 mg/kg)
AQ (10 mg/kg SD) in ACD, DDCs, FTDs and SLP (adult SD 1000/50 mg) in PCD	SLP (adult SD 1000/50 mg)+PQ (0.75 mg/kg SD)				

A brief analysis of ignoring the voice of dissent

Success largely depended upon the well-developed healthcare services system (Active case detection, Drug Distribution Centre, and Fever Treatment Depot), but the coverage of healthcare services was too limited then, and it was apparent to face failure in the case of weak healthcare delivery system. The greatest extent of success would have been possible in areas (labeled as sensitive to chloroquine) where the healthcare delivery system is considerably working better or areas where the clinical diagnosis was possible through the microscopic measurement of parasitemia (passive case detection).

After confirmation of blood infection, the treatment directed to clear blood infection and in order to prevent relapse, primaquine regimen of 5 days recommended as a radical cure in case of vivax malaria and three times increasing single dose recommended in case of *P. falciparum* Malaria without knowing the status of G6PD deficiency in India. Despite knowing the fact, primaquine used earlier in NMEP known to have toxic effects and proved lethal in patients with G6PD deficiency.

The broad Implications were as follows:

- The area labeled resistant or sensitive, and individuals of the community had to receive the antimalarial drugs. The patients living in the resistant-labeled area had to receive much higher doses than patients' living (notified) in the sensitive labeled area in any case of fever. Within these areas, patients identified from passive case detection had to receive high dose antimalarial medicine combinations
- Patients would receive presumptive treatment (in case of any fever) because of poorly developed healthcare systems irrespective of their immunity and nutritional status
- Non-immune patients might benefit from the prevention of mortality (unexplored) in *P. falciparum*, but they have to accept the

adverse effects of antimalarial drugs

- Relief in morbidity would be the subject of healthcare principally along with nursing care, while the patient with relative immune status and poor nutritional status would, of course, bear the cost of this drug overload, resulting in a weak/poor/absent healthcare delivery system
- In the case of confirming diagnosed *P. falciparum* case, the treatment regimen based on the label of the area rather than the sensitivity status of an Individual and patients living in the resistant-labeled area had to receive high dose antimalarial medications
- In the case of mass drug administration or migration, all migrants were to be treated as a confirmed case of *falciparum* Malaria from a sensitive labeled area. Thus, subject to give the highest dose of medications irrespective of their immunity and nutritional status

Further, G6PD deficient patients have to be lucky enough to get a prescription from the medical practitioner with sound epidemiological and pharmacological knowledge regarding malaria and drugs like primaquine if they want to remain safe from lethal effects-the responsibility to prevent the patients from higher doses placed on medical practitioners. The points mentioned above have the potential for this formal policy to be examined on the grounds of Public Health ethics, as discussed by [13].

First major change in 1995

The drug policy revised in the light of increased reported cases and several large Epidemics. The PHCs were stratified as high-risk areas and low-risk areas within the earlier labeled sensitive and resistant areas based on *falciparum* case reporting and recorded Malaria deaths.

The treatment guidelines were not changed for the patients notified from PHCs as low-risk areas in both resistant and sensitive labeled areas.

The changes were done to adopt for the patients notified from PHCs as high-risk Areas. In the case of presumptive treatment, Chloroquine dose was increased and high expectations from drugs went to such extent that the policy even recommended weekly prophylaxis of chloroquine and proguanil.

Table 2. Major changes in antimalarial drug policy 1995

Presumptive Treatment	Treatment after confirmation		Special Groups		
	***P. falciparum* Malaria**	***P. vivax* Malaria**	**Severe Malaria**	**Malaria in Pregnancy**	**Chemoprophylaxis or MDA**
CQ (10 mg/ kg SD)	CQ (10 mg/kg SD)+PQ (0.75 mg/kg SD)	CQ (10 mg/kg SD)+PQ (0.25 mg/ kg for 5 days)	Parenteral CQ or quinine	Contraindications PQ	MDA in migrants: CQ (10 mg/ kg)+PQ (0.75 mg/kg)
CQ (25 mg/ kg over 3 days)+PQ (0.75 mg/ kg SD)	**CQ Sensitive:** No further Treatment **CQ Resistant:** SP (Adult dose 1500/75 mg) with PQ (0.75 mg/kg SD)	+PQ (0.25 mg/kg for 5 days)	Parenteral Artemisini derivatives or quinine	___“”___	**CQ Sensitive:** CQ (10 mg/kg LD then 5 mg/kg weekly) **CQ Resistant:** CQ (5 mg/kg weekly)+proguanil (100 mg daily)

Next series of changes

The review of drug policy in 2001 continued the 1995 recommendations, but the criteria for designation of chloroquine-resistant areas changed by more than 25% of treatment failure in at least 30 patients of one PHC reporting more than 25% cases. This change seems a net widening exercise as acceptance for accommodation of reported drug resistance.

The drug load increased in 2004 for the confirmed cases of *vivax* and *falciparum* from low-risk areas.

Till 2005, all areas labeled as sensitive (high risk or low risk) recommended higher drug loads while the areas labeled as resistant recommended AS+SP combination (AS=4 mg/kg daily for three days and SP=1500/75 mg/kg Adult dose) because of SP monotherapy resistance and WHO recommendations. In 2007, the criteria to designate an area as resistant changed, and the new criteria were more than 10% treatment failure in at least 50 patients from cluster of PHCs reporting more than 30% *falciparum* cases. The importance of clinical diagnosis and presumptive therapy abandoned under the influence of highly sensitive rapid diagnostic kit and high dose chloroquine (25 mg/kg) recommended in case of unavailability of laboratory diagnosis in 24 hours. The Primaquine 14 days regimen again recommended because of proved poor Efficacy of 5 days regimen. Quinine plus Tetracycline or Doxycycline recommended in case of treatment failure from the highest available drug combination and use of primaquine recommended to stop in the case of AS+SP therapy.

In 2008, the criteria to designate an area as resistant again changed, and the new criteria were more than 10% treatment failure in at least 50 patients from cluster of blocks reporting more than 30% *falciparum* cases. The negative RDK cases also recommended

providing a full treatment regimen.

In 2010, the primaquine (0.75 mg/kg SD) was added into the AS+SP combination again, increasing the drug load. In 2013, Artemether Lumefantrine (80+480 mg adult dose) recommended replacing combination in North East because of resistance to the SP.

KEY FINDINGS OF LITERATURE REVIEW

The key findings of research review are as follows:

- Antimalarial drug policy undermines the immune and nutritional status of both individual and community
- The criteria to designate chloroquine resistance has been changed significantly as net widening exercise allowing to accommodate increasing reported CQ resistance
- Antimalarial drug list expanded extensively (Since 1982 to 2013 and till date) and the increasing drug dose is proportional to disease transmission in region/area; both the factors increasing medicalization and drug load on the community
- The conceptual understanding of malaria remains within biomedicine domain evidenced by the fact that much of importance (over-reliance) given to individual level technical interventions like drugs that too; without considering immunity and nutritional status of both individual and community
- Indian Malaria experts/Planners seems confused (or ignoring) to differentiate between Malaria's behavior at individual level and community level. Thus, the Malaria planning lacks ethical consideration for resource allocation in Public Health Planning evidenced by the fact that large resources allocated to least effective intervention that serves the profit making purpose of private sector pharma industry largely
- Sufferings of the most impoverished household of community remain unaddressed in Health planning, as drugs to ill individual are not the intervention for the entire household

OUTCOMES OF ANTIMALARIAL DRUG POLICY

Mere inclusion of any single drug into policy does not necessarily mean that it has succeeded in achieving its desired objective. It consumes a large number of resources before to be added into drug policy as well as post implementing/post-marketing research regarding effectiveness, safety, and efficacy (all are variable), which seems costly exercise for the resource constraint country like India. Drugs further consume resources in manufacturing, storage, supply, and disposing of (If not used before expiry). Again, the well-developed health services system and accessibility to such a system needed to deliver the medicine to those who are in the most need in order to prevent mortalities and to relive morbidities. Moreover, the desired action of drugs, even in an individual, influenced by various factors such as the intrinsic property of the drug itself, degree of resistance shown by parasite, body size and weight of an individual and given nursing care, etc. Failure of one drug led to efforts and resources in search of the new drug, the cycle does not find an end, and obviously, it would have detrimental effects on overall health planning in resource-constrained settings.

The primary purpose of any policy for pharmacotherapy should be relief in the suffering of community, prevention of mortalities, reducing morbidities, slowing down the resistance, and reducing drug load in community with effective, efficacious, and safe drugs.

MALARIA RELATED MORTALITIES AND MORBIDITIES AFTER ANTIMALARIAL DRUG POLICY

It can be argued that antimalarial drugs have prevented mortalities and morbidities. However, the question would be obvious regarding the cost and claim would be questionable based on Figures 2 and 3 (increasing mortality trend and stationary morbidity for a long time after the introduction of the formal policy of pharmacotherapy).

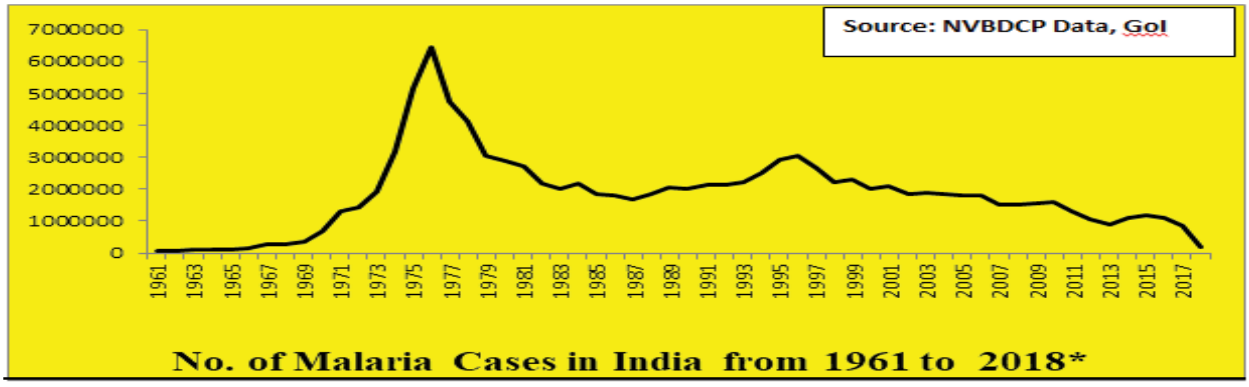

Figure 2. No. of malaria cases in India from the year 1961 to 2018 (up to July)

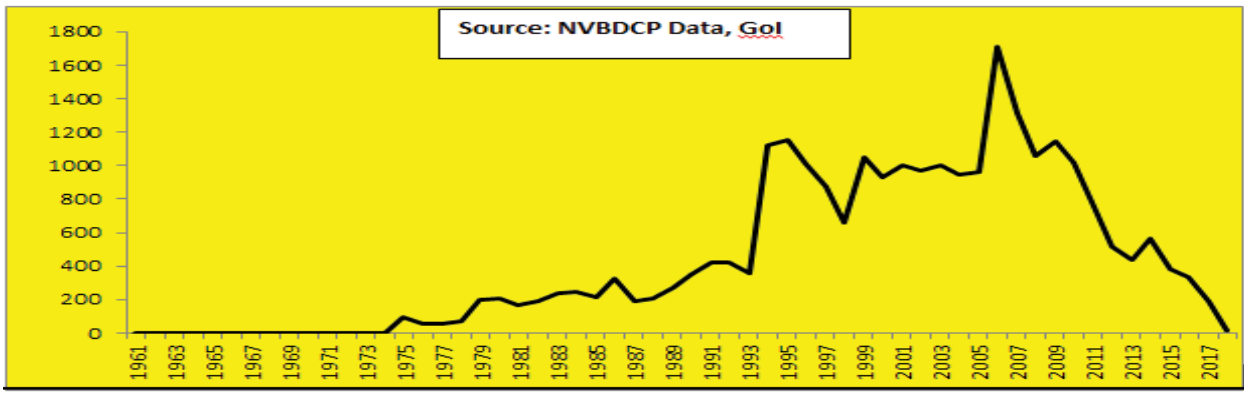

Figure 3. No. of malaria deaths in India from the year 1961 to 2018 (up to July)

It can be argued that indicators such as API, AFI, SPR, SFR, and ABER show improvement. The question is, does it work? Because these are program indicators only and reflect the trend, not the actual suffering; in other words, if clinical and diagnostic services under the malaria program abandoned, immediately all these indicators will show the highest performance, and we can live in the euphoria of the documental tackle of Malaria as Public Health Problem. Further, the extent of success in the prevention of mortalities and reduction in morbidities is unknown, and it is unknown who had benefitted? Furthermore, who had born the cost in complex Indian setting as it was not explicitly mentioned about directly associated factors of malaria-related morbidities and mortalities.

DRUG LOAD IN COMMUNITY

It is quite understandable and visible that the list of Antimalarial drugs has been expanded; consuming extensive resources and drug load on the community has been increased significantly. The community labeled as resistant or high risk and living in an area where healthcare services system weak/poor/absent has consumed and still consuming a larger proportion of this drug load irrespective of their individual immunity, nutritional status, and vulnerability.

ANTIMALARIAL DRUG RESISTANCE

The argument in favor of slowing resistance is questionable because the criteria to designate an area as resistant have been changed continuously, and it seems like a net widening exercise. It may also be possible that parasite strains might have gone significant changes and resulted in developing resistance continuously towards antimalarial medications in the underdeveloped health system. It suggests an unending fight between drug and parasite strain, which points out the limitations of antimalarial drugs, and again the introduction of new drugs, would require considerable resources.

RELIEF IN SUFFERING OF COMMUNITY BY ANTIMALARIAL DRUGS

It is often advisable not to take medicine too frequently because each medication has specific side effects beside desired effects, ranging from mild to severe. The role of drugs as medicine for the treatment of any illness starts after losing opportunities to prevent the infection or disease in the non-immune population.

The current list of antimalarials includes only blood schizonticides and tissues schizonticides, and these drugs are known to clear the only specific stage of the specific parasite. There is no single antimalarial available, which can clear all the stages of all parasites [3]. Not a single antimalarial is proven totally safe as every drug has adverse effects and varying degree of tolerability while WHO recommends pharmacovigilance for monitoring safety. Proven efficacy of these antimalarial drugs ignores the role of host immunity, which prevents the failing drug from appearing effective [14]. Radical treatment using primaquine has been proved to have little epidemiological and clinical significance in any case in the endemic area where transmission potential remains high [15].

It is advised not to take any drug on an empty stomach because of severe side effects [3], and the safety of the poorest from adverse effects of drugs would be compromised under the fear of *P. falciparum* mortality. Thus, it becomes vital to take note of immune and nutritional status.

As antimalarial medications undermine the role of individual immunity, current allopathic Antimalarial pharmacotherapy might work only in the areas where transmission is negligible, the more significant proportion of the population is non-immune, nutritional status of the community is considerably better and the healthcare services are fairly developed. Still, the relapse/recrudescence can't be prevented for sure. However, where the larger proportion of the population possesses immunity because of repeated exposure, the transmission is possible, healthcare services are poor/weak/absent, and the nutritional status of the community is poor, the poorest had to suffer the most and resource allocation would not worth.

It does not mean to say that we should leave it and let the people die, the response is of course needed, but critical planning in

resource allocation would maximize the benefits. Otherwise, it would again prove false waves of optimism for Malaria eradication/ control as public health problem from India in existing healthcare delivery system ignoring the suffering of poorest, the role of immunity and nutritional status of both individual and community.

Application of individual case management approach (largely focusing on antimalarial drugs) to the community by obscuring the differences between individuals and community and differences within the community would be an obstacle in tackling Malaria as Public Health Problem.

If the use of medicines can't be avoided in public health program, there are simply two ways:

- If an area is labeled as resistant/sensitive, program should follow intervention for the area rather than individuals of area and
- If the program is following case management approach then each individual of community should be treated separately for their resistant or sensitive status considering immune and nutritional status at both individual and community level

It should be acknowledged that the least could be accomplished while investing a large number of resources following current allopathic Antimalarial pharmacotherapy because it has a limited or minimal role in the public health program and the suffering of the most impoverished individual/household remains unaddressed.

Thus, Policy for Pharmacotherapy is unable to serve its primary purpose of relieving suffering of community, prevention of mortalities, reducing morbidities, slowing down the resistance, and reducing drug load in community.

DISCUSSION AND CONCLUSION

Maximum share of global malaria sufferings (approx. 90% of global malaria related morbidities and mortalities) reported from Africa. The above-mentioned graphs of malaria related mortalities and morbidities trend from 1961 to July 2018 corroborates the fact that malaria is a significant public health problem in the subcontinent. It has also been pointed out that we (India) are dealing with the tip of the iceberg of malaria, and long term planning is required [16] and the accurate estimation data of malaria mortality and morbidity is not available. However, it is quite clear that the Indian population suffers because of malaria, as India has the most considerable share in malaria-related morbidities and mortalities in the South East Asia Region of WHO. Thus, there is no doubt that malaria has relevance as a public health problem in subcontinent [17,18].

It is important to note that both *P. falciparum* and *P. vivax* parasites prevail in India, and the possibility of mixed infections in an individual remains high. It can be predicted that considerable immunity must be present in a complex Indian setting. It has been noticed that tropical strains have more risk of relapse. Thus, epidemiological picture of malaria in Indian context becomes complex because there are several factors contribute in it [19], while different paradigm of malaria (such as tribal, rural, urban, industrial and border malaria) has been defined in the Indian context and each of these requires specific approaches [20].

The experience since the NMEP to current days has told that malaria transmission can't be ceased without comprehensive measures. Even if it breaks, success can't be sustained in India where geographical and environmental conditions are favorable for Malaria transmission, the healthcare delivery system is inadequate and weakly developed or even absent in some areas, and larger share of the population is malnourished. India has also experienced the limitations of technologies and their harmful environmental effects. Many factors had played a significant role in Malaria transmissions such as migration and development projects such as green revolution, rail network, road network, and dam constructions [21]. Faulty engineering in development projects had a significant role in Malaria transmission and epidemics [22]. Further, several characteristics disqualify malaria from being a suitable infectious disease for eradication [23].

Health planning is a comprehensive exercise that would need integration of all related disciplines (with addressing politics of knowledge), and the maximized role of public sector Institutions in interdisciplinary research for Public Health would be crucial. Critical evaluation of the recommendations of any national or international organization needed to predict the implications in complex Indian context with acknowledgement of limitations explicitly. Every policy or program decision must be critically examined through the public health ethics framework because accountability is greater on policymakers. Thus, they have the responsibility to accommodate the voice of dissent.

Before embarking on the global saga of malaria eradication or control through the public health program, there is a need to learn from previous experiences (including NMEP and historical) [24]. A response strategy to malaria should consider the present stage of the country's social, political, economic development, and cultural context with an epidemiological lens to relieve the suffering of the most impoverished individual/household and to achieve sustainable success.

In the light of epidemiological complexity, it can be emphasized that overall socioeconomic development would be crucial as inequalities of health distribution and inequities of healthcare access [25] interlinked to malaria related morbidity and mortality. Thus, the context-specific concept of health, as suggested by Priya et al. [26], should be considered in order to achieve health for all.

The emphasis should be placed on start from the people and planning with public health ethical consideration for justified utilization of available resources to relieve the sufferings of the most impoverished household because human factors can't be tested in a laboratory. Instead, it needed to be experienced from the field and applied for action.

***Issues and Reasons would be various. The solution is not the simple one without a strong political will for reforms to facilitate equitable and sustainable socioeconomic development, but what least could be done immediately to relieve suffering and for provision of public health*:**

- Planners and implementers of health service system should be clear about the distinction between the behavior of Malaria and strategies to tackle it at the Individual and community level
- The starting can be done with the revival and strengthening of effective public health engineering until ensuring water supply and sanitation for most impoverished household as an intervention and preventive measure to relieve their sufferings. It will eventually contribute to health provision and control the vector population without any harmful effect on any individual or environment
- Strengthening and effective implementation of PDS (with improvement in the image of the existing program in community) would provide considerable relief to the poorest households and eventually lead to an improvement in the nutritional status of the community
- Strengthening and effective implementation of employment schemes (such as MGNREGA) and pension schemes would be crucial for improving living standards and eventually reducing malaria-related morbidities and mortalities

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