

**NATIONAL
DRUG SURVEY**
2014 - 2016

Chapter 1

Background



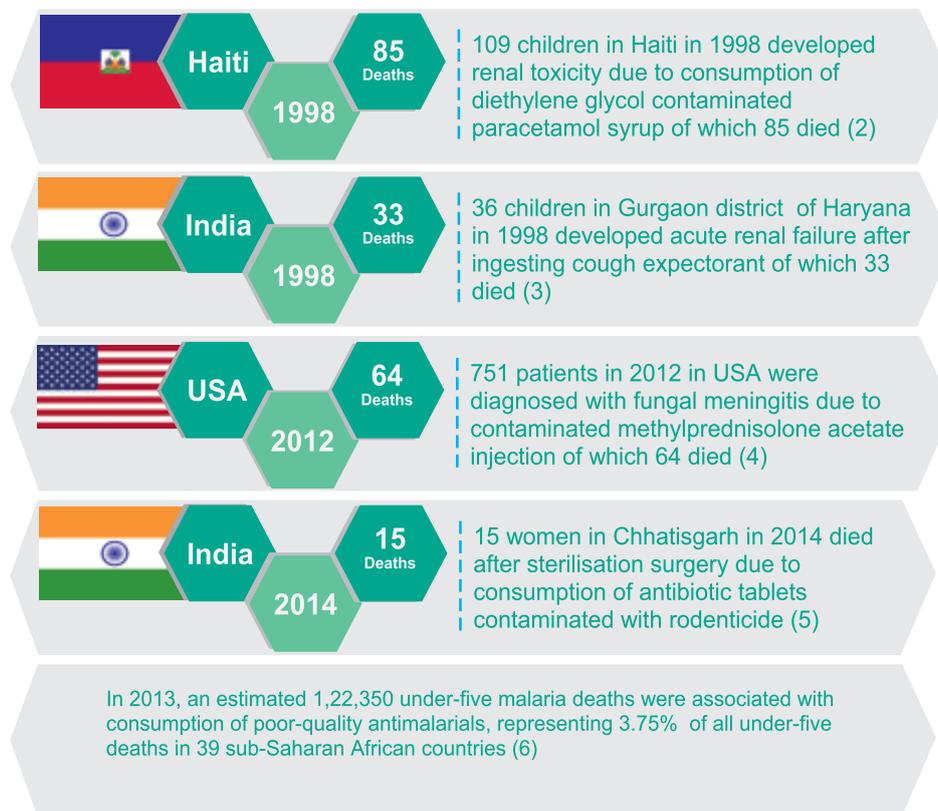
Background

Drug related morbidity and mortality are phenomenon of therapeutic malfunction and/or failure of a therapeutic agent to produce therapeutic effect/benefit outcome. This outcome is linked to quality of medicines at different points of supply chain.

GLOBAL SCENARIO

Globalization of the pharmaceutical industry is rapidly spreading poor-quality medicines worldwide even before adequate detection and intervention can be made. Considering the scale of the global pharmaceutical industry (USD 1050 billion) and the incidence of potentially fatal diseases, even a small amount of poor-quality medicine is unacceptable as it would increase Drug related morbidity and mortality (1).

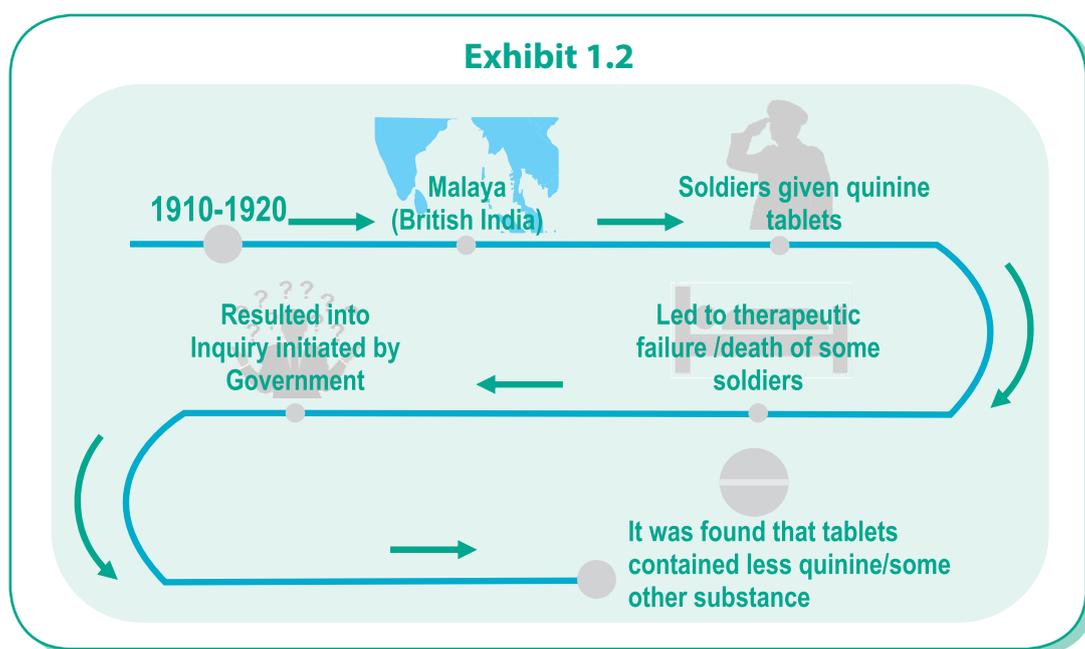
Exhibit 1.1



The existence of NSQ/Spurious Drugs is a global phenomenon. Trade in NSQ/Spurious Drugs affects both developing and developed countries and India is no exception. The NSQ/Spurious Drugs adversely impact on human safety and it could sometimes cause a grievous injury and even death due to failure of therapeutic intervention. The impact of poor-quality medicines is most clearly evident if they contain harmful impurities, incorrect active ingredients or improperly formulated products since patients may suffer from adverse/lethal effects (Exhibit 1.1). For diseases, such as Tuberculosis, HIV and Malaria which are treated with combination therapy, poor-quality of combination medicines lead to spread of resistance.

In many reports, it is unclear if poor-quality medicines are NSQ or Spurious, but it is important that they are correctly classified because they have different origins and different solutions. Inadequate enforcement, lenient penalties, corruption, 'spaghetti-like' trade arrangements, unregistered medicines, and ignorance of poor-quality medicines among the public and health workers exacerbate the situation. The available evidence suggests that poor-quality essential medicines are having a very important but avoidable toll on health in the developing world, and that this issue clearly needs to be taken much more seriously (1).

At the World Health Assembly in May 1988, many countries expressed concern about counterfeit Drugs circulating in their markets. The Assembly adopted a resolution, which requested the Governments and pharmaceutical manufacturers to cooperate in the detection and prevention of Falsely labelled, Spurious, Counterfeit or Substandard Drugs(7). Though, the prevalence of





poor quality and Spurious Drugs has been reported from developed as well as developing countries, comprehensive global data regarding the extent of this problem is not available.

CONCERNS IN INDIA

In India, the problem of Substandard, Spurious and Adulterated Drugs was noticed during early part of 20th century. In the beginning of the 20th century, Drug industry was practically non-existent in India and Drugs were imported. Some of the products were of inferior quality and harmful for public health (Exhibit 1.2)(8).

The First World War changed the situation and both the Indian and foreign companies started manufacturing pharmaceutical formulations at cheaper rates to compete with imported products.

During 1920-1930, marketing of harmful substitutes and adulterants in place of genuine Drugs was detected as revealed in various reports. It was as early as 1927, Sir Haroon Ebrahim Jaffer of Bombay Presidency moved a resolution in the Council of States, asking the Governor General to take immediate measure to control the "craze for medicinal Drugs by legislation for standardisation of the preparations and sale of such Drugs"(9).

Meanwhile, it was pointed out that traders were flooding the market with Drugs and chemicals of defective strength and impure quality and even sera and vaccines were being freely sold to the public without any quality test and boosted up by so-called unsolicited testimonials from non-existent individuals (9).

Print media, especially the Indian Medical Gazette, Statesman and Civil & Military Gazette championed the need for legislative interference to prevent adulteration of Drugs. According to Indian Medical Gazette, there was no control over the manufacturing, sale and distribution of Drugs in India. In the absence of legislation, which could directly prevent Drug adulteration or assure conformity to proper standards of purity and strength, unscrupulous foreign traders who had settled in India started dumping Substandard, Adulterated and Spurious Drugs (9). For some indigenous medicinal preparations as well, there was no protocol for standardization of preparations and Drugs were indiscriminately used. For Indian manufacturers, the concern was more to do with the poor quality ingredients. Bengal Pharmaceutical and Chemical Works founded by Acharya P. C. Ray, was already aware of Spurious Drugs, as became evident from its advertisement, which cautioned: "Beware of Spurious and worthless imitations of our preparations (9)."

In 1931, the unsettling demand for regulation of quality of medicines led the Indian Government to appoint a Drugs Enquiry Committee under the Chairmanship Lt. Col. R. N. Chopra. The Committee was asked to make sifting enquiries into the whole matter of Drug production, distribution and sale by inviting opinions and meeting concerned people. The Committee was asked to make recommendations about the ways and means of controlling the production and sale of Drugs and pharmaceuticals in the interest of public health. The Chopra Committee toured all over the country and after carefully examining the data placed before it, submitted a voluminous report to the Government (10). The outbreak of the Second World War in 1939 delayed introduction of legislation on the lines suggested by the Chopra Committee which the Indian Government contemplated and considered as urgent. However, with the ascent of the Governor General, on 10th April 1940, the Drugs Act, 1940 was enacted (Exhibit 1.3). The stage was now set for legislative control of import, manufacture, distribution and sale of Drugs in India (10).

Exhibit 1.3

CHOPRA COMMITTEE (1931) <ul style="list-style-type: none">• Suggested creation of Drug regulating authority at the centre and in provinces.• Recommended establishment of a well-equipped Central Drugs Laboratory• Recommended establishment of Drug quality control laboratories in provinces and also at the centre.	DRUGS ACT (1940) <ul style="list-style-type: none">• Regulation for import, manufacture, distribution and sale of Drugs.• Drugs Technical Advisory Board was constituted in 1941 as per Act• Drug Rules were framed in 1945 to give effect to the provisions of the Act
HATHI COMMITTEE (1974) <ul style="list-style-type: none">• Recommended that states should constitute a legal-cum-intelligence cell for carrying on the campaign against Spurious Drugs• Recommended enlistment of medical, other professions and consumer councils in combating Spurious Drugs.	MASHELKAR COMMITTEE (2003) <ul style="list-style-type: none">• Central Government should provide assistance for study to estimate the extent of Spurious Drugs• The consumers and health professional to play active role to create awareness about Spurious Drugs• More stringent penalties for offences relating to Spurious and Sub-standard Drugs



GOVERNMENT INITIATIVES IN INDIA

The period 1971-1995 proved important in laying down a solid foundation of the Indian pharmaceutical industry. As a consequence, India became supplier of essential Drugs for domestic consumption and export. India was able to demonstrate its proficiency in the manufacture of generic Drugs during this period(10).

Following the suggestions made in Parliament, in 1974 the Government of India in the Ministry of Petroleum and Chemicals, set up the committee on Drugs and Pharmaceutical Industry with Shri Jaisukh Lal Hathi as Chairman and Dr. P. R. Gupta, Adviser (Drugs) as Member-Secretary to inquire into the progress made by the Drug industry and on other related matters including the measures that may be recommended by this Committee for effective quality control of Drugs (11).

The Hathi committee had then identified the long term effects of Spurious Drugs as follows: *“The problem of Spurious Drugs should be tackled effectively and on a priority basis as otherwise Drug faking activities may reach alarming proportions and pose a grave danger to health of the nation ... Lastly, our exports will suffer a serious setback if wide spread reports on the movement of Spurious Drugs continue to be published in newspapers or discussed in the Central and State legislatures.”*

In 2003, Government of India set up another Expert Committee for “A comprehensive examination of Drug regulatory issues, including the problem of Spurious Drugs” under the Chairmanship of Dr. R. A. Mashelkar, Director General, CSIR. The Committee observed that: *“there has been a wide-ranging national concern about Spurious / Counterfeit / Substandard Drugs. The Hon’ble Supreme Court of India, the National Human Rights Commission and the Members of Parliament have time and again expressed a concern about improving the Drug regulatory system in the country. The Drugs and Cosmetics Act has not been reviewed in a comprehensive manner since its inception although the Rules have been amended from time to time. The Government of India, in the past, had constituted several Committees, which had examined the issues and had made many recommendations. These recommendations have been implemented by the Government to some extent, but the core issues have remained unresolved (12)”.*

In 2008, the Government of India amended the Drugs & Cosmetics Act to enhance the penalties for various offences related to spurious and adulterated Drugs.

DRUG QUALITY SURVEYS IN OTHER PARTS OF THE WORLD

In order to get further insights into the problem, a review of 47 Drug quality Surveys published between 1992-2015 was carried out. Majority of the published Drug quality Surveys have been carried out in South East Asia and Sub-Saharan Africa. There are very few studies from North America, Europe and Oceania. These Surveys were evaluated against 14 quantitative as well as qualitative criteria. Admittedly, large majority of previous Survey protocols were developed with focus on only a few of these criteria and were limited in their scope (Exhibit 1.4 and references in Annexure 3).



Exhibit 1.4 14 Limitations of Previous Drug Surveys –1

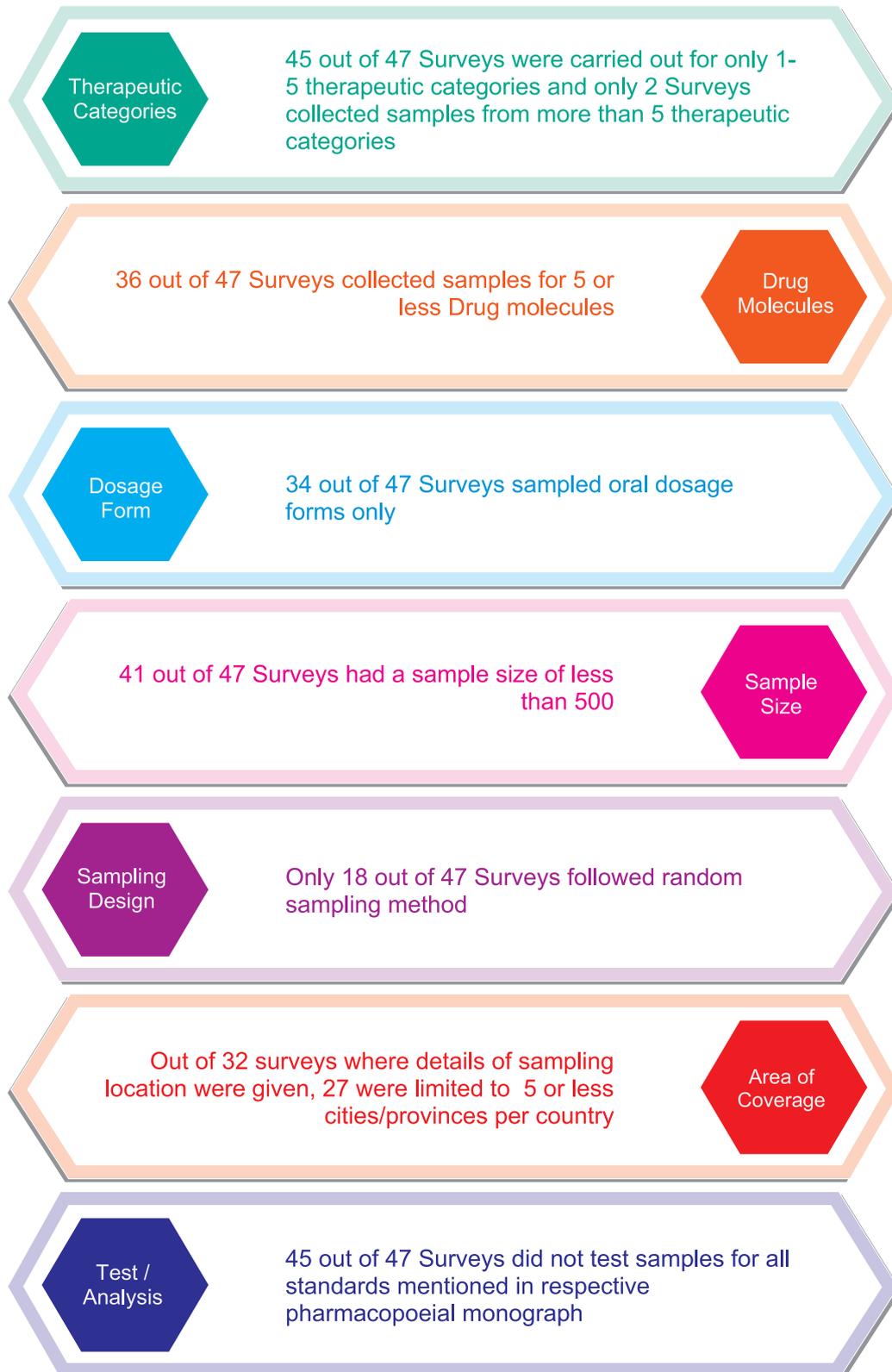
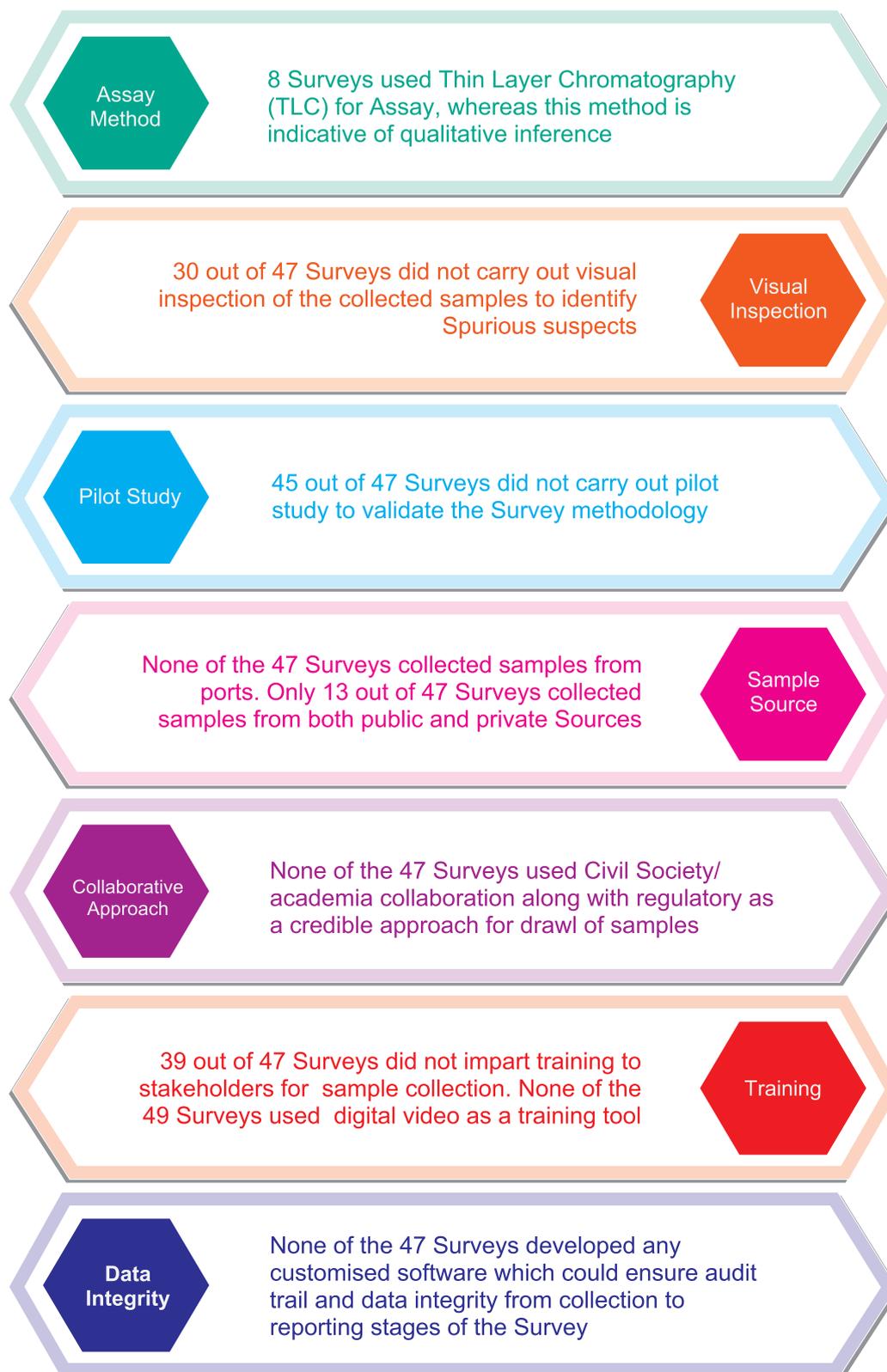


Exhibit 1.4 14 Limitations of Previous Drug Surveys –2





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