

- (v) further, it has been made mandatory to submit the following details in the clinical trial/new drug application of New Chemical Entity and Global Clinical Trials:-
- Assessment of risk versus benefit to the patients.
 - Innovation *vis-à-vis* existing therapeutic option.
 - Unmet medical need in the country.
- (vi) Expert Committees have been constituted to examine the reports of deaths in clinical trials. These Expert Committees have prepared detailed guidelines for examination of reports of deaths and also prepared formula(s) for determining the quantum of compensation in case of clinical trial related deaths and injury (other than death).
- (vii) In compliance of the order dated 03.01.2013 of the Hon'ble Supreme Court, a system of supervision of clinical trial has been put in place by constituting an Apex Committee under the chairpersonship of Secretary, Health and Family Welfare; and a Technical Committee under chairmanship of Director General, Health Services (DGHS).

Outside defecations causing chronic infections

2333. DR. L. HANUMANTHAI AH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government is aware that about half of Indians defecate outside without using toilets and from here, children pick up parasites and chronic infections that impair the ability of their intestines to absorb nutrients;

(b) if so, the details of the number of Diarrhoea affected children admitted and treated in various hospitals of the country;

(c) whether Government has taken note that the UNICEF reports death of almost 117,000 Indian children per year from Diarrhoea;

(d) if so, the measures taken by Government to curb the said alarming situation in the country; and

(e) the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI ASHWINI KUMAR CHOUBEY): (a) and (b) As per National Annual Rural Sanitation Survey (NARSS) in 2017 done by World Bank, 77% of the household were found to have access to the toilets during the survey period.

The administrative data available on Swachh Bharat Mission — Gramin portal, the sanitation coverage is 89.4% as on date.

Diarrhoea among the children is caused by poor child care practices such as poor hygiene practices among care givers including poor hand washing practices, non-availability clean drinking water and other infections etc.

The details of the number of Diarrhoea affected children admitted and treated in various hospitals is not maintained centrally.

(c) As per UNICEF data*, 102,813 under-five children died due to diarrhoea in 2016.

(d) and (e) In order to control childhood diarrhoea and generate awareness on water, sanitation and hygiene (WASH) practices in the community, an Intensified Diarrhoea Control Fortnight (IDCF) is being implemented in the country since 2014 under National Health Mission. The ultimate aim of IDCF is 'zero child deaths due to childhood diarrhoea'. The key activities during IDCF are as follows:—

1. Home visits by ASHA workers to every household that have under-five children. During the visit, they will
 - (i) distribute ORS sachet
 - (ii) counsel on seeking care in case of diarrhoea so that Zinc can be provided by the ASHA
 - (iii) provide message of continued feeding during diarrhoea
 - (iv) demonstrate and counsel on preparation of ORS through mothers group meetings
2. Establish 'ORS-Zinc corners' - at medical colleges, district hospitals, block health facilities and other treatment sites of Government. Similarly, in partnership with IAP these corners will be established in every clinic of paediatric treatment facilities.
3. Hand washing demonstrations and practices in schools.
4. Intensive awareness generation through TV, radio, miking, banners, posters at strategic locations.
5. Multi-sectoral involvement for better impact such as rallies, competitions at schools, State and district level launch by leaders, involvement of IAP, involvement of PRIs through meetings in presence of Block Medical Officer, mother meetings and ORS demonstrations at Anganwadi Centres.

*UNICEF data available in web link: <https://data.unicef.org/topic/child-health/diarrhoeal-disease/>, accession date : 3.08.2018.