among 2–65-year olds,[12] after a booster dose given 10 months after a 2-dose primary series.[12] A field effectiveness case-control study in Mozambique, during a mass oral cholera vaccination program in an endemic population aged ≥2 years, found that 1 or more doses of the inactivated oral cholera vaccine was 78% protective (1–6 months after the 1st dose). The per-protocol effectiveness of 2 doses was 84% (0.5–4.5 months after the 2nd dose).[15]

There is structural similarity and immunologic cross-reactivity between the cholera toxin and the heat-labile toxin of *E. coli*, which is often associated with 'travellers' diarrhoea'. Therefore, it had been suggested that the rCTB-containing vaccine may also provide protection against heat-labile toxin producing enterotoxigenic *E. coli* (LT-ETEC). A study in short-term Finnish tourists[16] showed that the inactivated oral cholera vaccine also provided a 60% reduction in diarrhoea caused by LT-ETEC. A study in Bangladesh, an endemic area, showed 67% protection against LT-ETEC for 3 months only.[17] It can be expected that the inactivated vaccine will reduce the proportion of travellers' diarrhoea that is caused by LT-ETEC. Approximately 30 to 40% of travellers to developing countries contract travellers' diarrhoea, with an average of 20% of cases caused by LT-ETEC; hence, the 60% efficacy of the oral inactivated vaccine against LT-ETEC could be expected to prevent up to 15% of travellers' diarrhoea.[18-20] However, in Australia this vaccine is only registered for the prevention of cholera.

To date, there is no vaccine marketed in Australia to protect against infection with *V. cholerae* O139. An oral killed whole-cell bivalent cholera vaccine (against both serogroups O1 and O139) has been evaluated in Vietnam.[21,22] More recently, in India, an interim analysis of a cluster-randomised controlled trial reported a protective efficacy of 67% against *V. cholerae* O1 after 2 years. Specific efficacy against *V. cholerae* 0139 could not be assessed in this study, as cholera episodes caused by this serogroup were not detected.[23]

4.1.5 Transport, storage and handling

Transport according to *National vaccine storage guidelines: Strive for 5*.[24] Store at +2°C to +8°C. Do not freeze. Protect from light.

Because the person to be vaccinated will be responsible for looking after the vaccine following purchase, details of how it should be transported (from pharmacy to home) and stored in the refrigerator (at home) must be carefully explained.

4.1.6 Dosage and administration

Dukoral is an oral vaccine.

Food and drink should be avoided for 1 hour before and 1 hour after administration of the inactivated cholera vaccine, as the vaccine is acid labile.

Children aged 2–6 years

Three doses are required, given a minimum of 1 week and up to 6 weeks apart. If an interval of more than 6 weeks occurs between any of the doses, re-start the vaccination course.

Dukoral is administered orally. After dissolving the buffer granules in 150 mL of water, half the solution is then poured away and the entire contents of the vaccine vial are mixed with the remaining 75 mL for administration.

Adults and children aged >6 years

Two doses are required, given a minimum of 1 week and up to 6 weeks apart. If the 2nd dose is not administered within 6 weeks, re-start the vaccination course.

Dukoral is administered orally. After dissolving the buffer granules in 150 mL of water, the contents of the vaccine vial are then added to the solution for administration.

Co-administration with other vaccines

The inactivated oral cholera vaccine can be given with, or at any time before or after, other travel vaccines, such as yellow fever or parenteral Vi polysaccharide typhoid vaccines.

However, there should be an interval of at least 8 hours between the administration of the inactivated oral cholera vaccine and oral live attenuated typhoid vaccine (see 4.1.10 *Precautions* below).

4.1.7 Recommendations

Vaccination against cholera is not an official requirement for entry into any foreign country.

Routine cholera vaccination is not recommended as the risk to travellers is very low, despite the endemicity of cholera in some countries often visited by Australians. Careful and sensible selection of food and water is of far greater importance to the traveller than cholera vaccination.

Cholera vaccination should be considered for travellers at increased risk of acquiring diarrhoeal disease, such as those with achlorhydria, and for travellers at increased risk of severe or complicated diarrhoeal disease, such as those with poorly controlled or otherwise complicated diabetes, inflammatory bowel disease, HIV/AIDS or other conditions resulting in immunocompromise, or significant cardiovascular disease.

Cholera vaccination should also be considered for travellers with considerable risk of exposure to, or acquiring, cholera, such as humanitarian disaster workers deployed to regions with endemic or epidemic cholera.

Dukoral is not registered for use in children aged <2 years and is not recommended for use in this age group.