Standing up for refugees

The Lancet is wrong to suggest that the Royal College of Paediatrics and Child Health (RCPCH) has not advocated on behalf of children caught up in the refugee crisis (Editorial, Sept 12).[1] We have welcomed the UK Government's commitment to accept more refugees, but have also urged the leadership not to play politics with the world's most vulnerable infants, children, and young people.

The UK should lead the international community in ensuring that children of all ages, exposed to appalling risks as they flee their homes, are provided with safe passage, health care, social support, and protection against exploitation, and should do the utmost to prevent separation from their families.

Half the world's forcibly displaced people are younger than 18 years; 7600 unaccompanied children arrived in Italy this year.[2] The tragic death of 3-year-old Alan Kurdi epitomises their unacceptable suffering. The RCPCH has made clear our disappointment at continuing reluctance by the UK Government to make a categorical commitment to protect affected children.

The choice for the UK and Europe is stark. Either we fail to support these vulnerable children and, in so doing, severely compromise their ability to adapt and integrate into their adoptive societies, rendering them more susceptible to radicalisation, or we act with humanity and create a new generation of young people with the kinds of hopes, aspirations, and abilities that Europe's economies so desperately need.

Children are children, wherever they happen to be. It is simply unacceptable to duck the moral responsibility to protect them.

We declare no competing interests.

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1 The Lancet. Adapting to migration as a planetary force. *Lancet* 2015; **386:** 1013.

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The rights of children arriving in Europe

The number of refugees who attempt to reach Europe is increasing, and, as warned in an Editorial (Sept 12, p 1013),[1] decisive action is needed.

European Union (EU) member states have to do more to ensure the care and protection of these vulnerable refugees, especially the children. Every day, children around the world are severely affected by crises and circumstances that are beyond their control.

UNICEF reports an alarming situation in Europe—more than 106 000 children applied for asylum in the EU (between January–June, 2015).[2] Since the beginning of 2015, more than 122 380 migrants have arrived in Italy, more than 12 120 of whom were children.[3] Many of these children are alone. According to Save the Children Italy, 8715 children arrived in Italy without family or guardians since the start of the year.[3] About a thousand people land on the Dodecanese islands every day.[4] In June alone, 4270 children landed on the islands, and 86 of them were unaccompanied.[4] Many of the children who travel unaccompanied come from Eritrea, Somalia, Egypt, and South Africa. These children are in serious danger once they arrive in Europe as they could disappear into criminal groups, become victims of child trafficking, or be forced into manual labour, domestic work, drug smuggling, or prostitution.

For many migrants, Italy and Greece are a bridge into EU countries. However, the burden cannot fall on Italy and Greece alone: the EU bears collective responsibility for dealing with the crisis. The European nations have a collective role in ensuring that refugees and migrants are treated with dignity and that vulnerable children are protected. The EU has the duty to prevent children from being exploited by unscrupulous human traffickers and to give these children their unquestionable rights to health, safety, and wellbeing. EU member states can prevent children from becoming deprived of their childhood with all the psychological implications this could inflict on the rest of their lives.

Robert Getss/dpa/Corbis

The European Academy of Paediatrics (EAP) urge all European medical societies to help find a humane solution to the current crisis. The EAP believes that it is necessary to create a platform for countries to discuss and share issues affecting paediatric services in Europe, provide medical and psychosocial support services for children, and to protect them. We call on EU member states to ensure that children gain access to legal services and school and are protected from from violence, abuse, and exploitation. Paediatricians should cooperate with schools to help these children receive health care (including mental health screening, and immunisations). The EAP advocates for medical care without barriers, inequities, and inequalities for all children in Europe and solicits governments of nations receiving migrants to protect and defend children's rights, without restrictions, because these children have the same rights to receive care as other European children.

All children have the right to live in a safe environment where they can grow up and achieve their potential. There must not be a right or wrong place to be born.

We declare no competing interests.

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Palliative care in complex humanitarian crisis responses

We welcome the recent Editorial (Sept 12, p 1013)[1] about the refugee crisis in Europe, challenging the "weak or non-existent" response of health-care institutions to the ongoing complex humanitarian crisis.

WHO has called on health professionals to respond appropriately by providing adequate care and protection.[2] However, palliative care—an approach that improves the quality of life of patients and their families who have life-threatening illness through the prevention and relief of suffering by means of early identification and correct assessment and treatment of pain and other problems, whether physical, psychosocial, or spiritual[3]—has been entirely omitted from relief strategies, despite the 2014 World Health Assembly Resolution 67 calling for palliative care to be integrated into health systems.

Minimal work has been undertaken to identify and address the palliative care needs of people in the current complex humanitarian crisis who have life-limiting illnesses and whose social and medical needs are exacerbated by dislocation. Palliative care should be an integral part of the humanitarian emergency response strategy and should include provision of essential medicines (eg, oral morphine for moderate-to-severe pain) to meet patients' urgent needs.

A new network—Palliative Care in Complex Humanitarian Emergencies (PALCHE)—has been formed to address existing shortcomings in the integration of palliative care into responses to medium-term (eg, natural disasters) and long-term humanitarian emergencies (eg, refugee camps). This network aims to work with response agencies, generating awareness of unmet needs and improving the quality of life of those with palliative care needs.

Addressing the health needs of people who are displaced by humanitarian crises honours their human rights.[4]

We declare no competing interests.

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Post-authorisation assessment of orphan drugs

The EU regulation of orphan drugs has promoted the development of new treatments for rare disorders.[1] However, the high cost of most orphan drugs threatens the sustainability of public health care. Unfortunately, the effectiveness of treatment is often unclear for part, if not all, of the patient population, especially for patients with very rare diseases, such as inherited metabolic disorders. We believe that the system of post-authorisation assessment for orphan drugs needs to be reformed to address these problems. Fast access to high quality data is essential for the improvement of treatment options and to manage costs more effectively.

Fabry disease, a rare X-linked multisystem disease,[2] is an example of an orphan disease that would benefit from reform of the post-authorisation assessment system. Storage of glycosphingolipids leads to small fibre neuropathy, progressive renal failure, heart failure, and stroke.[2] However, the disease course is dependent on the type of mutation, sex, and environmental factors. In 2000, agalsidase alfa and agalsidase beta were authorised for the treatment of Fabry disease at a mean cost of €200 000 per patient per year. Authorisation was based on pivotal trials with short follow-up, strict inclusion criteria, and the use of intermediate endpoints. Consequently, the effectiveness of the enzymes on clinically relevant endpoint measures was unclear. Post-authorisation needed the initiation of two separate pharmaceutical company-driven registries, which led to fragmentation of data. In the Netherlands, a cost-effectiveness analysis was required as part of a national reimbursement regulation. The unfavourably high incremental cost-effective ratio of €3 million per quality-adjusted life-year fuelled public discussions about the cost of orphan drugs. Data from only one phase 4 trial,[3] published several years after the pivotal trials, showed that enzyme therapy can delay the onset of new complications. All other studies have either been from one of the two separate drug registries, with astonishingly small datasets, or small, single-centre studies.[4]