Letter to the Editor

Organisational strategies for the safe management of intravenous iron therapy: a revolutionary tool for implementing Patient Blood Management

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Dear Sir,

It is now common knowledge that iron deficiency anaemia (IDA) is a global health problem, affecting many millions of people worldwide. Although oral iron should be the first therapeutic option in many instances, in specific conditions, intravenous (IV) iron can be the product of choice to favour a prompt haematopoietic recovery. Last generation IV iron compounds seem to provide a high safety profile. However, with the aim of minimising the risk of delayed recognition and treatment of serious hypersensitivity reactions, in 2013, the European Medicines Agency (EMA)[1], as part of the document entitled "New recommendations to manage the risk of allergic reactions with intravenous iron-containing medicines", stated that "*Intravenous iron medicines should only be administered when staff trained in evaluating and managing anaphylactic and anaphylactoid reactions are immediately available as well as resuscitation facilities*". In Italy, this has limited IV iron administration exclusively to in-hospital use, despite the fact that severe allergic reactions (mainly induced by the carbohydrate moiety surrounding the iron core) are exceptionally rare.

In this context, the document entitled "Organisational strategies for the safe administration of intravenous iron therapy in non-hospitalised settings", published by the Emilia-Romagna Regional Health Service in July 2020[2], is worthy of note. This is the first document of its kind in Italy and provides recommendations to establish standardised organisational procedures favouring safe IV iron therapy in outpatient settings over a wide territorial area (**Table I**). Furthermore, this strategy can be rapidly implemented in non-hospital contexts without the need for specialised medical or nursing staff. The

Table I - *Synopsis of recommendations from Emilia-Romagna, Italy, for organisational strategies and the safe management of intravenous iron therapy*

Recommendations	
1.	The prescriber must evaluate the case by discussing it with the medical staff of the transfusion services.
2.	Each Local Health Unit must identify facilities where the administration can be organised, devising a specific protocol with the indication of the devices to be included on the emergency trolley.
3.	First Aid training for facility personnel is mandatory.
4.	Local Health Units may define collaboration agreements with other public or private bodies accredited with the necessary safety requirements in order to increase the number of suitable locations for administration.
5.	Local Health Units will be able to evaluate the implementation of innovative organisational solutions such as providing an adequately trained and equipped team to carry out administrations in remote locations or in facilities that do not meet the safety requirements set out in the company operating protocol (e.g., residential care homes for the elderly, the patient's home).

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only training requirement concerns the need for prompt recognition and treatment of severe adverse reactions of IV iron use, along with the standard familiarity with the equipment and emergency drugs on a resuscitation trolley. The above-mentioned regional document puts the EMA's recommendations into practice, allowing a simplified but more extensive management of patients affected by IDA. This measure may be implemented wherever outpatient treatment programmes are in place, taking advantage of mobile staff and multiple point-of-care testing facilities to cover limited catchment areas. The cautionary EMA statements are even more valuable in the light of the Italian law no. 24/2017 on "Healthcare safety", which mainly focusses on measures for the prevention and management of adverse events[3,4].

In our opinion, the treatment of IDA as a means to improve patient quality of life and to reduce the risk of transfusion, in accordance with the first pillar of the Patient Blood Management principles[5], should be one of the main objectives of an advanced health care system. The document published by the Emilia-Romagna Regional Health Service can be used as a model to promote the implementation of effective therapeutic programmes outside the hospital. In spite of this, Transfusion Medicine experts continue to be role players, providing recommendations on individual cases for the most appropriate therapeutic approach. Our aim is to stimulate debate by means of an international survey to collect information concerning the methods used in other countries to promote the safe administration of IV iron in non-hospital settings.

DISCLOSURE OF CONFLICTS OF INTEREST

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