



# 8 YEARS EXPERIENCE: HAEMOVIGILANCE SYSTEM IN IRAN SINCE 2009



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**Iranian Blood Transfusion Organization**



# INHS(Iranian National Haemovigilance System)



- Introduction
- Implementation
- results
- Strengths
- Weaknesses



# Country Profile

- 80000000 population
- about **2100000 donation** per year( 25.6 blood donations per 1000 population.)
- 927 hospitals(807 hospitals out of 927 established haemovigilance system till now)
- 135000 active hospital bed
- 31 haemovigilance province office( the number of staff : 40)
- 1 haemovigilance office in IBTO headquarter (the number of staff: 9)

# IBTO and INHS

- IBTO was established in **1974** as a centralized organization with its provincial blood centers affiliated to the central headquarters within the scope of laws, regulations and guidelines
- **1984** the new IBTO constitution in which it was assigned the sole responsible body for ensuring supply of safe and adequate blood was ratified by Iran parliament and the Red Crescent was entitled to hand over all its centers, duties and human resources involved in transfusion activities to IBTO
- In **2009 INHS(Iranian National Haemovigilance System)** established in IBTO headquarter



# Defination

- Haemovigilance is a set of surveillance procedures covering the **whole transfusion chain** from the collection of blood components to the follow-up of its recipients, intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of blood products, and to prevent their occurrence and reoccurrence.
- The main goal of Haemovigilance systems is to **prevent adverse transfusion reactions for increasing patient safety**



# Haemovigilance, as a safety concept

- For improving patient safety, having **integrated system** for reporting is necessary.
- In Iran, more than 2,1000,000 units of blood are donated voluntarily each year, from which different products are prepared and then are distributed to various private and public hospitals. In other words, providing required blood components of all medical centers is responsibility of Iranian blood transfusion organization (IBTO) which is a centralized organization.
- Haemovigilance system is a mandatory system in Iran which is supported by MOH and since 2012, its implementation became mandatory in all hospitals.



# Terminology

***Appeared in the beginning of the 90s;***

***The term was probably created in France and has Greek and Latin roots:***

***“haema” = blood***

***“vigilans” = paying particular***



# What is haemovigilance?

- A set of surveillance procedures on undesirable events/effects along the whole transfusion chain
  - Systematic data collection
  - Regular analyses of data
  - Interpretation of results
  - Dissemination of results





# What is hemovigilance?

- Objectives
  - Prevent occurrence or recurrence of those undesirable events/effects
  - Establish priorities for intervention
  - Evaluate preventive measures



# Scope of national hemovigilance



- Surveillance of the transfusion process
  - Errors at blood center
  - Errors at the hospital
  - Traceability



# Major aims of haemovigilance



**To assure surveillance of the blood transfusion activities**

**To collect data on sequel of blood transfusion**

**To develop of local & national guidelines**

**To Reduce risk of adverse events in hospitals**  
**To improve transfusion standards**



# Requirements for establishing a national haemovigilance system



- Hospital
  - Personnel dedicated to blood safety
    - Transfusion safety officer
    - Blood bank director
    - Chief technologist
  - Role
    - Investigation and reporting of transfusion reactions and errors
    - Training
    - Oversee implementation of preventive measures

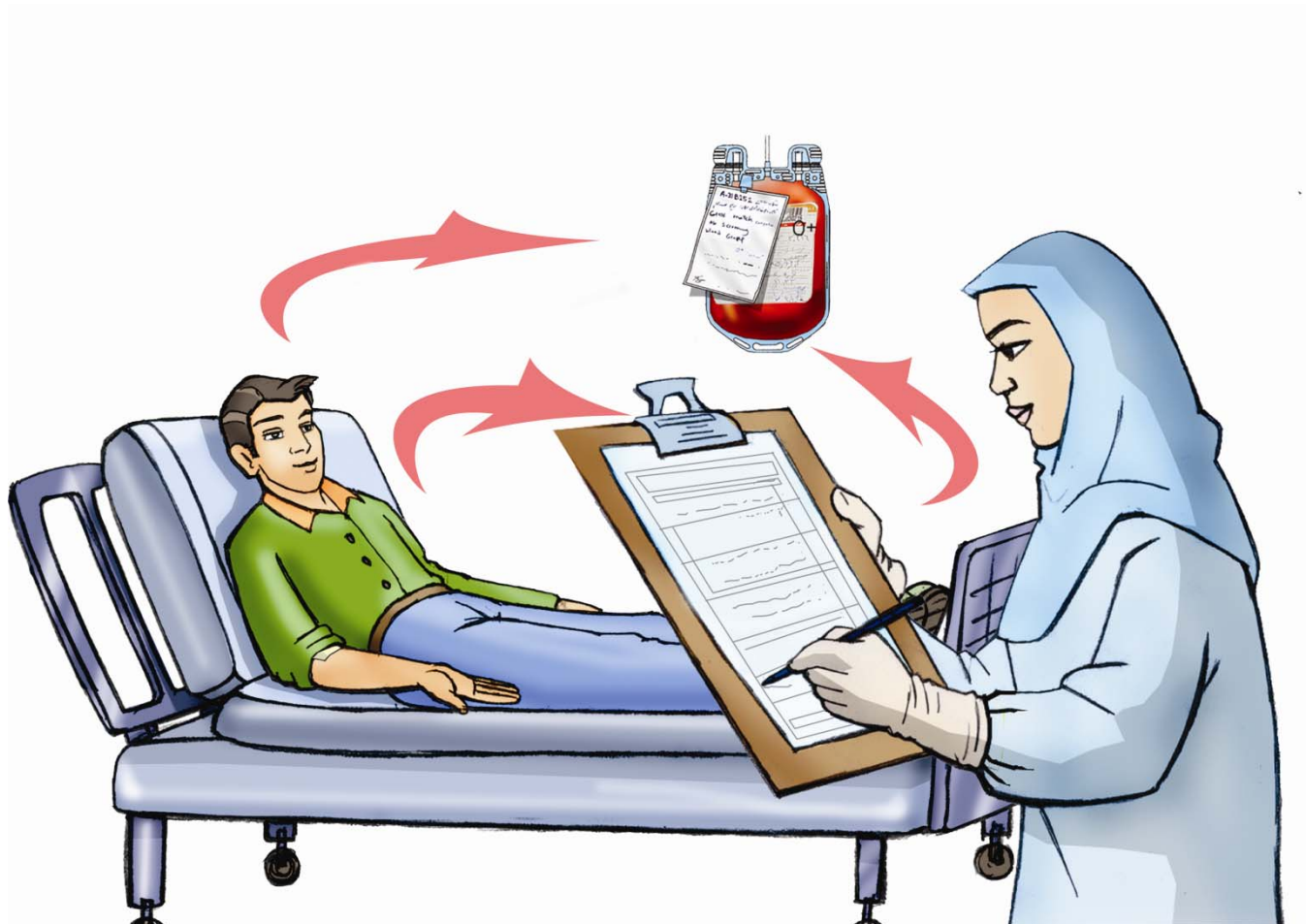


# Requirements for establishing haemovigilance



- Hospital
  - Transfusion committee
    - Multidisciplinary
    - Review transfusion reactions
    - Propose and evaluate preventive actions
    - Guidelines for appropriate utilization

# Retraining of nurses for pretransfusion checking and appropriate documentation



# Retraining of physician for diagnosis adverse reactions and the protocol for understanding the etiology of reactions



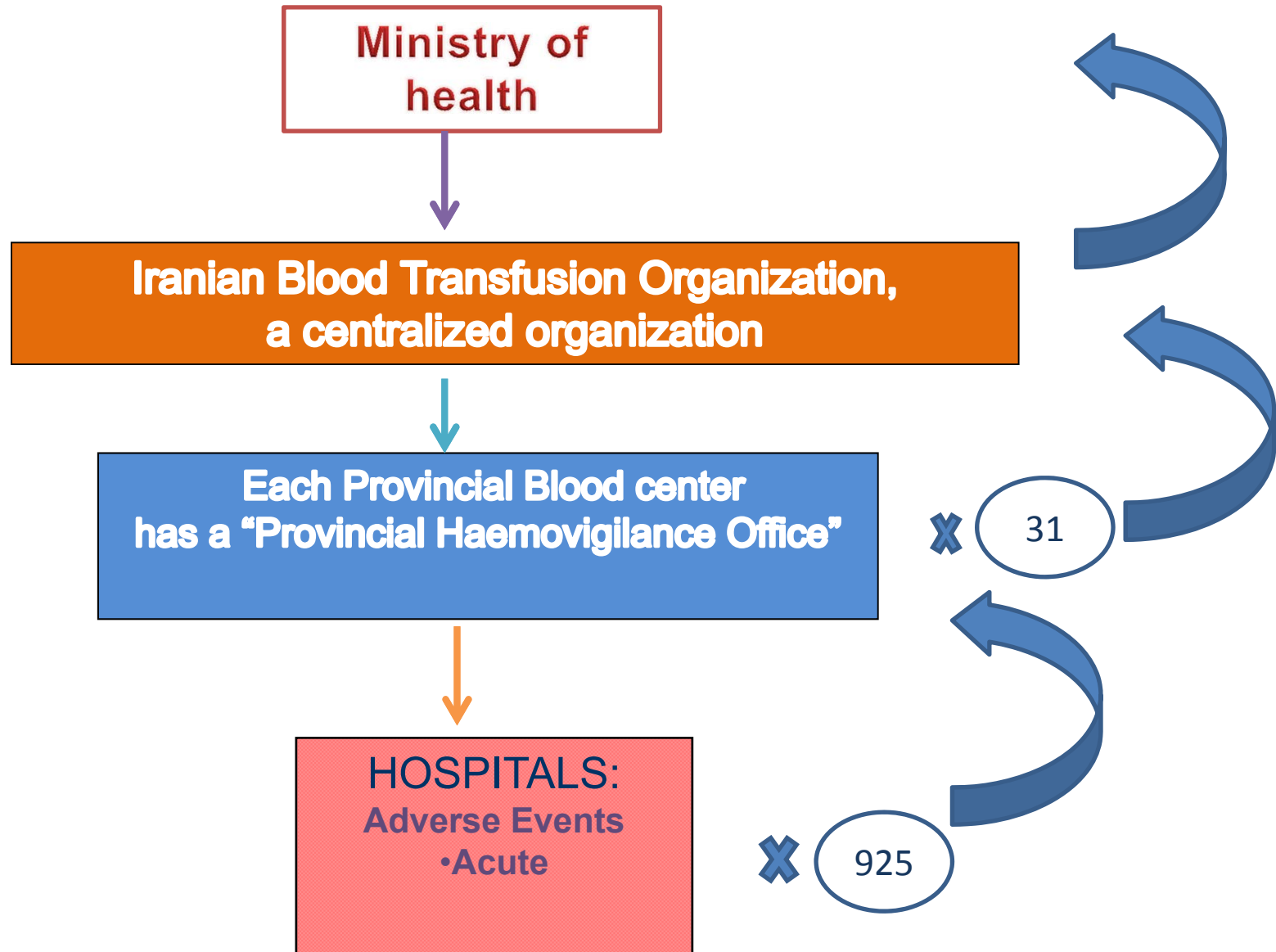
# Training of blood bank staff for standard procedures and protocols for adverse reactions follow up







# Infrastructure for National TAR Reporting



# Different Models in the World

+ Haemovigilance now in many European countries, USA, Canada, South Africa are performed.

Basically the existing systems can be classified

+ according to:

1. their legal status: **mandatory** vs. **voluntary**.

+ 2. their field of application: **all events** vs. **very serious reactions** in the patient,

3. their organisation: **strictly centralised** vs. **more**

+ **or less decentralised**

# Types of haemovigilance systems

IRAN	France	Singapore	Netherlands	UK
INHS**	Hemovigilance	Hemovigilance	TRIP*	SHOT
2009	1994	2002	2002	1996
Mandatory	Mandatory	Voluntary	Voluntary	Voluntary
Non-punitive	Non-punitive	Non-punitive	Non-punitive	Non-punitive
All reactions	All reactions	All reactions	All reactions	Only serious reactions

**\*Transfusion Reactions in Patients**

**\*\*Iranian National Hemovigilance System**



# SCOPE of INHS(Iranian National Haemovigilance System)

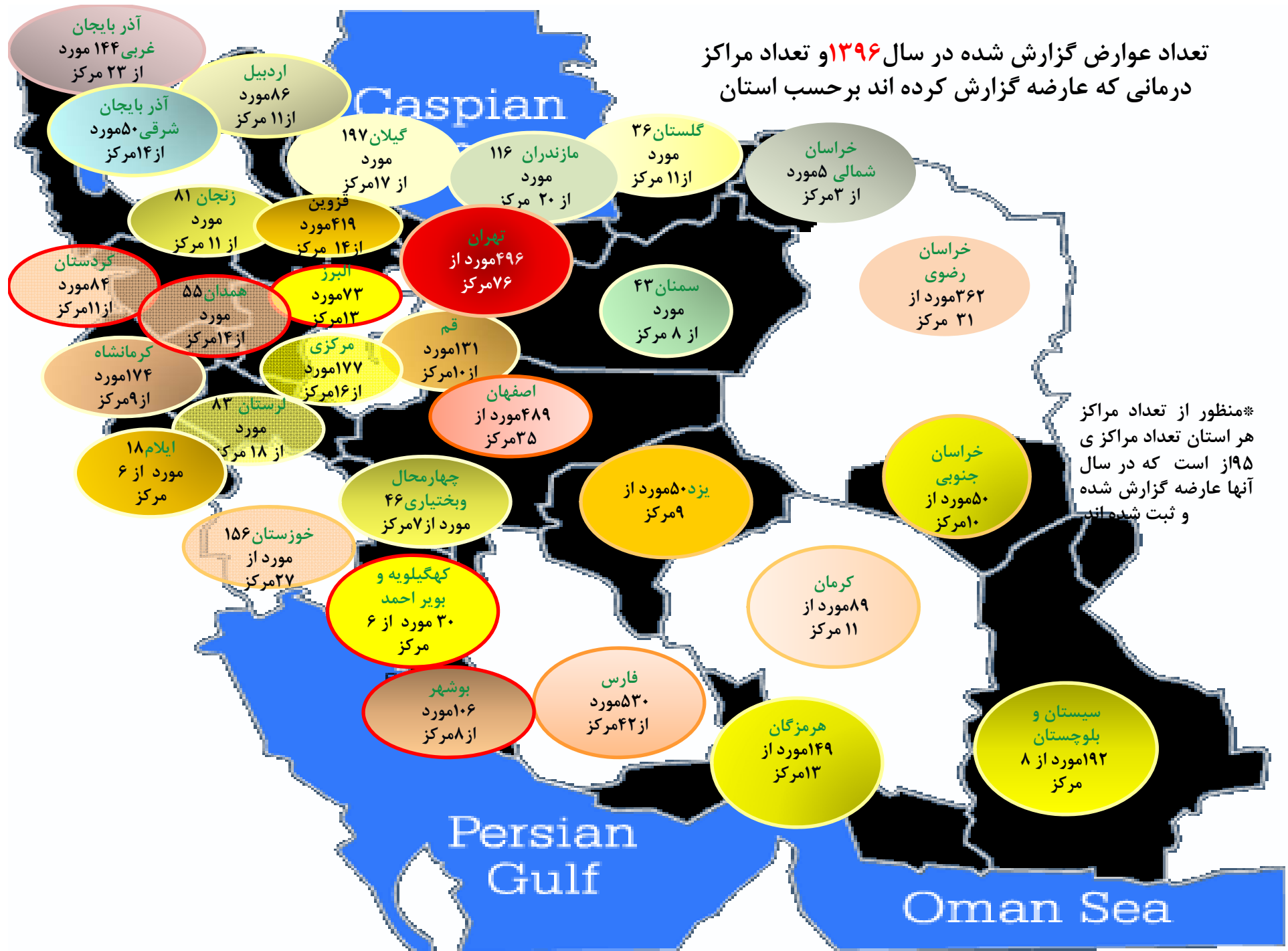
**+** INHS: **all blood components** encompasses issued by Blood Transfusion Services

**+** **All Adverse reactions**

**+** **All hospitals( public –private hospitals)**

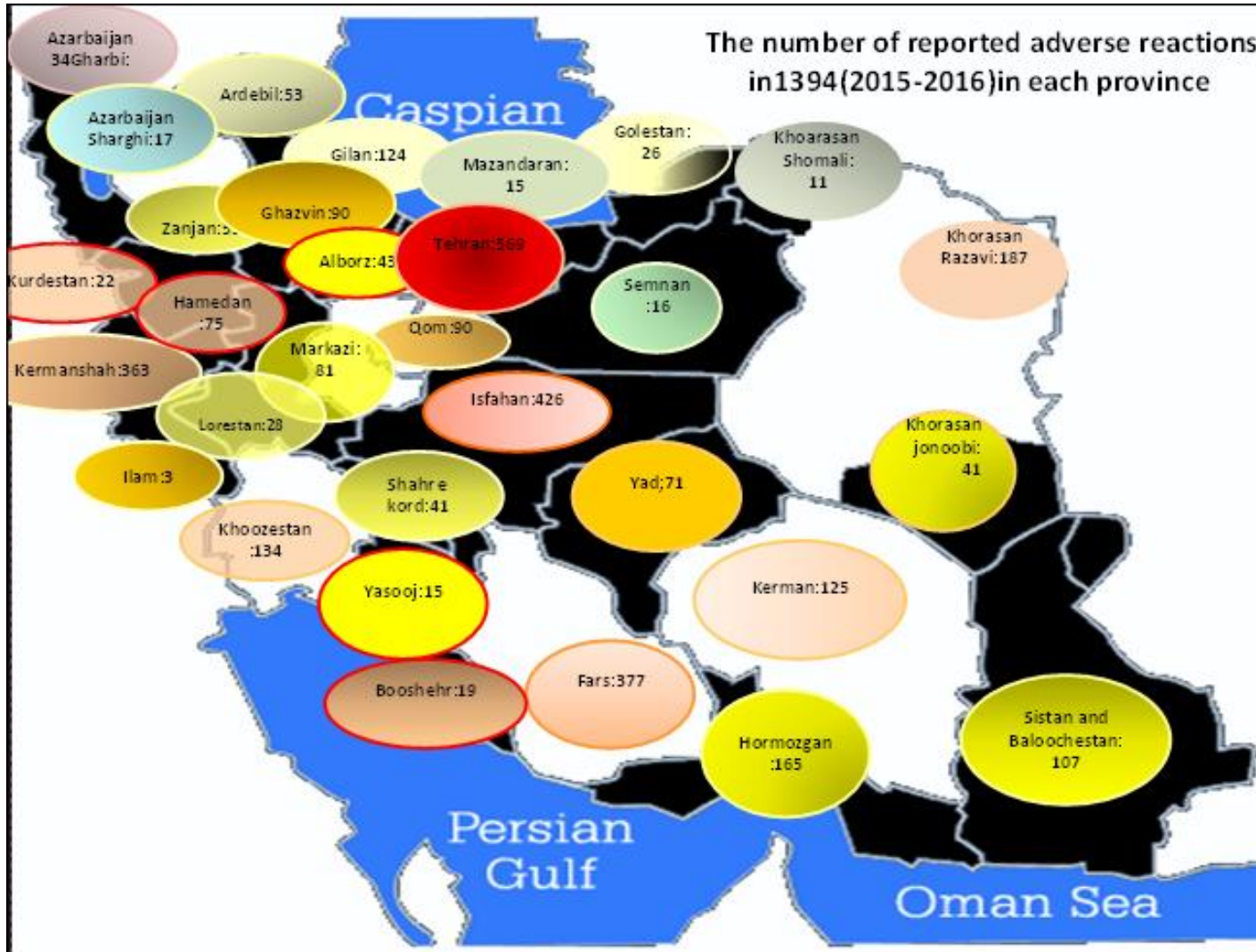
**+** Participation is **Mandatory by MOH (since 2012)**

## تعداد عوارض گزارش شده در سال ۱۳۹۶ و تعداد مراکز درمانی که عارضه گزارش کرده اند برحسب استان



\*منظور از تعداد مراکز هر استان تعداد مراکز می باشد که در سال ۱۳۹۵ آنها عارضه گزارش شده و ثبت شده اند

# Coverage: all of the country

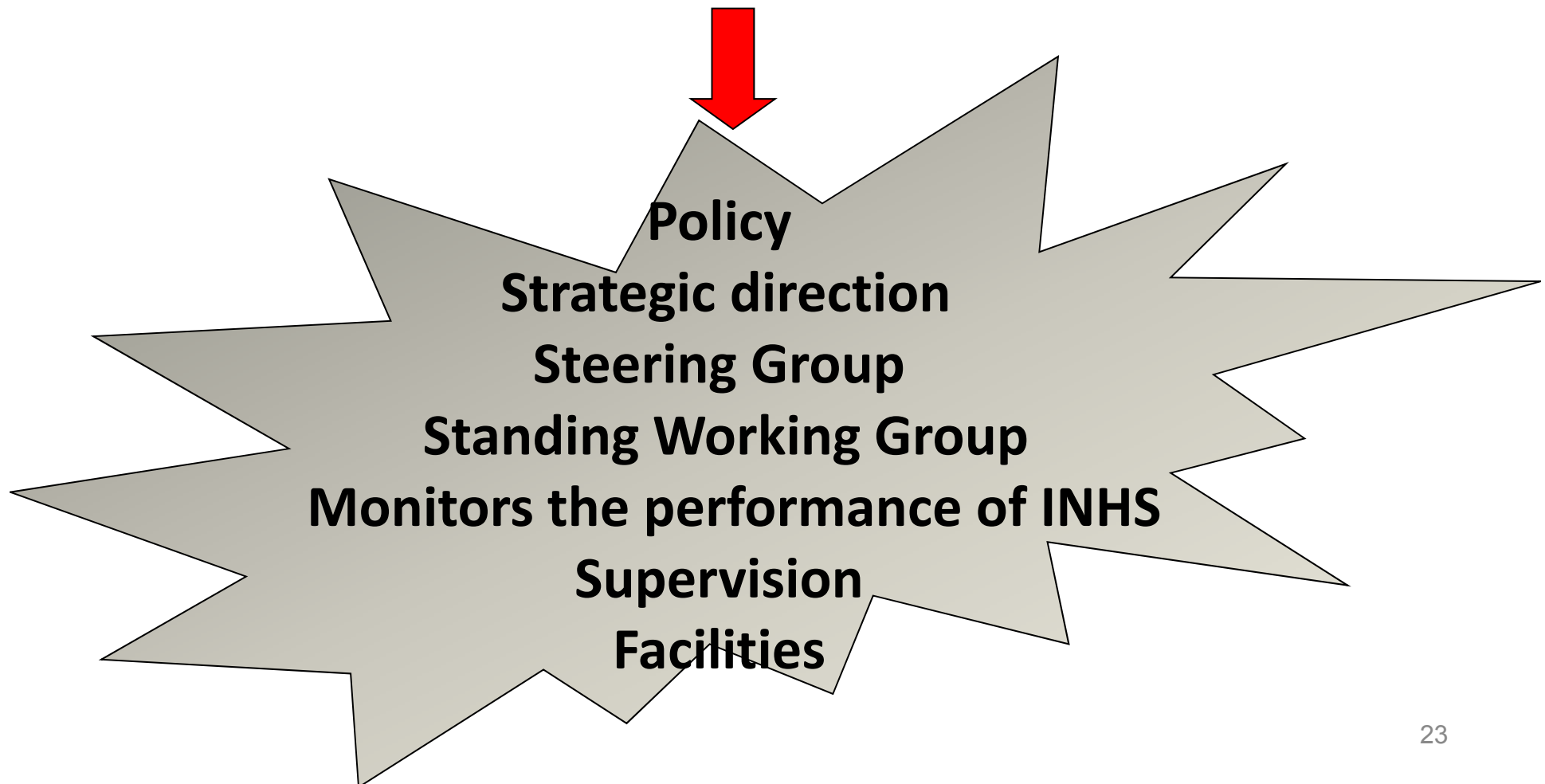




# Structure



**The Iranian Blood Transfusion Organization provides funding and resources for INHS**





# Our experience

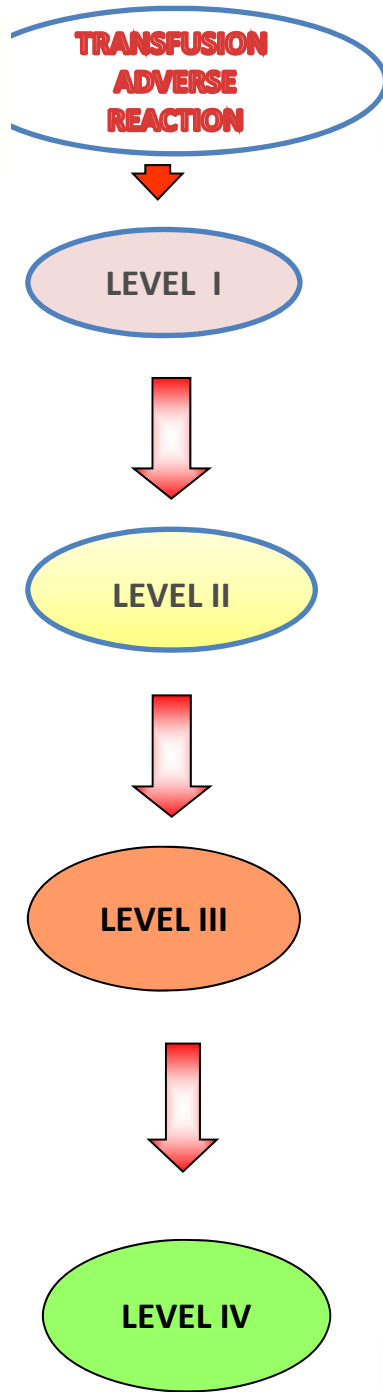
- We started our new system in 40 hospitals in Iran
- At the first we prepared the standard forms-slides-different guidelines need for haemovigilance system
- Now 781 hospitals out of 925 hospitals all over the country have haemovigilance system.



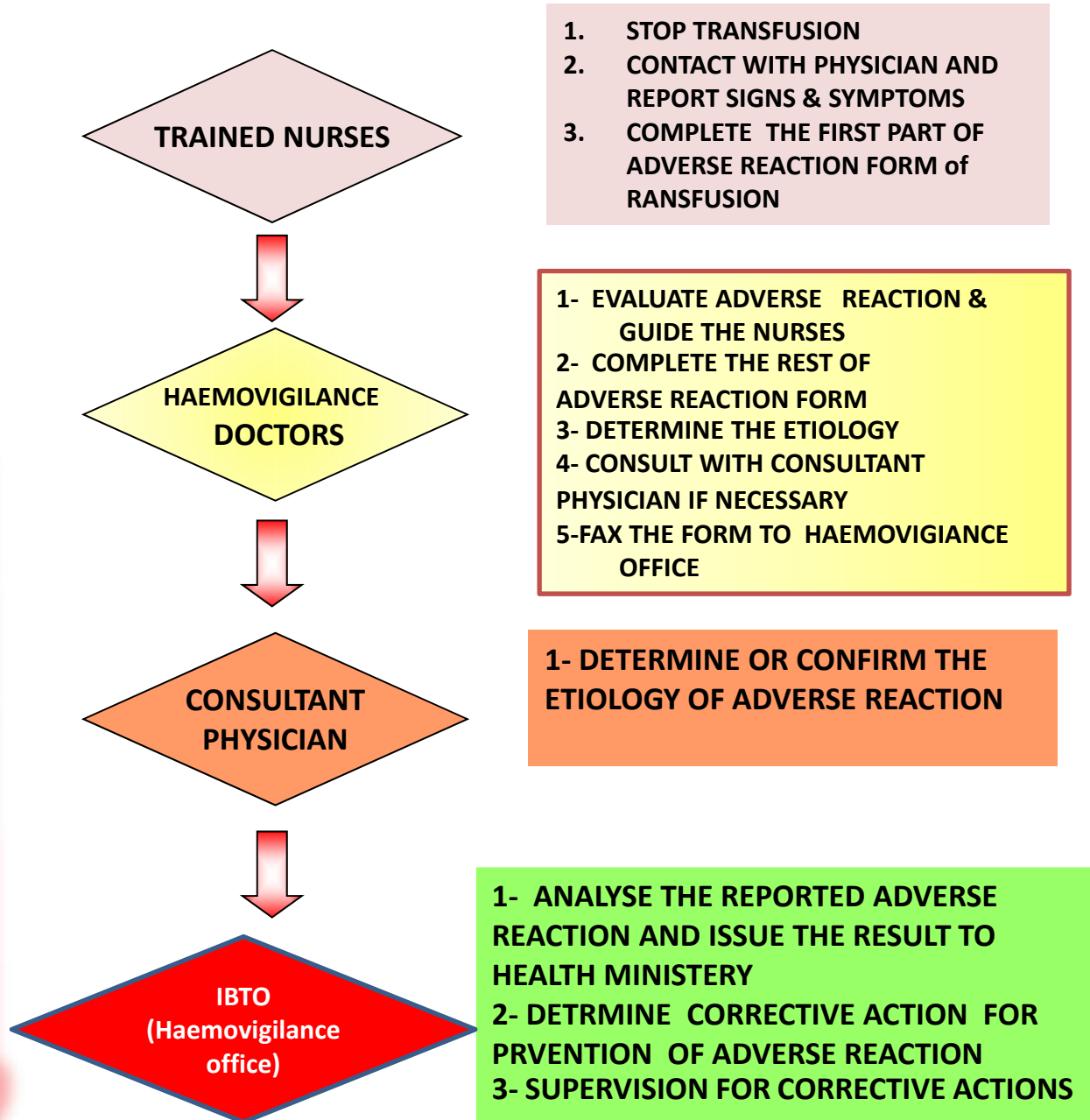


# Our experience

- Haemovigilance system is a **mandatory** system in Iran that is supported by the law and since 2009 this system was established in some hospitals as a pilot project, and then in 2012, its implementation became mandatory in all hospitals by MOH
- From January 2009 to September 2018 this system was established in **781 (84.4%)** hospitals (from 925 hospitals across the country).



## MANAGEMENT ALGORITHM OF TRANSFUSION REACTION IN HOSPITALS





# Implementation

- Trained physicians on Haemovigilance were responsible for diagnosis of ATR via filling in the manual form for every case identified.
- All hospitals have to use the same *blood transfusion adverse reaction report form* which has been prepared by central Haemovigilance office of IBTO.
- The Haemovigilance system calls for the registration of all kinds of immediate and delayed transfusion reactions.
- Since the blood components consumption was not available, therefore, the incidence of adverse effects was calculated based on the number of units of blood products distributed in hospitals.
- All information entered into the software SPSS version IBM23.



# Implementation

- All hospitals have to use the same *blood transfusion adverse reaction report form* which has been prepared by central Haemovigilance office of IBTO.
- The records were periodically sent in the first step to one of the 31 blood transfusion centers in the country and, after primary checking and in the second step to the central Haemovigilance office of IBTO for further evaluation.

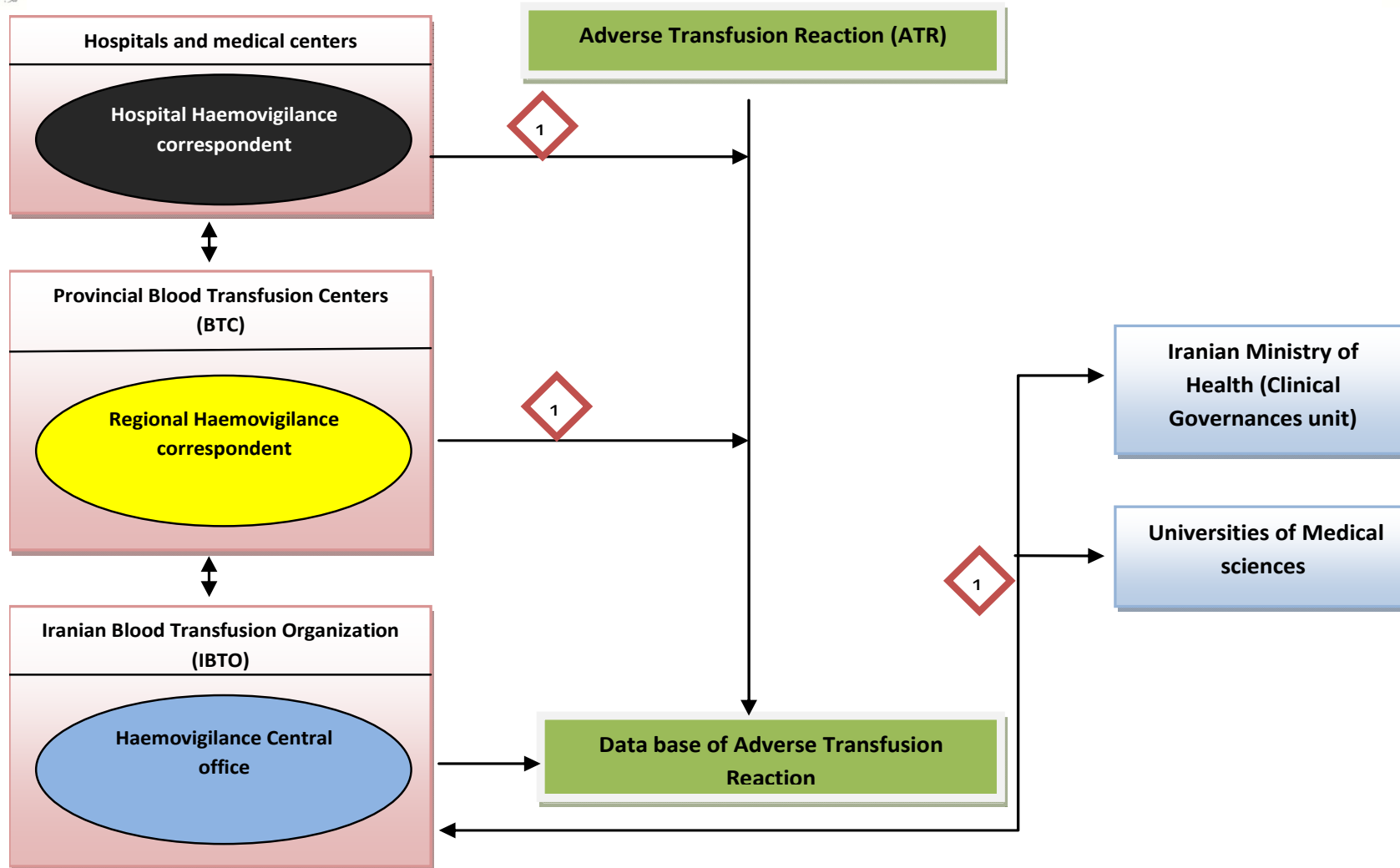


Figure 1. Members of the Haemovigilance network and ATR reporting pathway in Iran. 1= Paper or Electronic document transmitted by Fax and/or e-mail.



# activities

- From January 2009 to September 2018 this system was established in **781 (84.43%)** hospitals (from 925 hospitals across the country).
- Establishment of system requires educational course for physicians, nurses and blood bank staff about blood transfusion. Till September 2018 more than 15684 physicians', 72709 nurses and ---6162 blood bank personnel have been trained on Haemovigilance.
- Trained physicians on Haemovigilance were responsible for diagnosis of ATR (with using Control of Disease criteria ) via filling in the manual form for every case identified.



## The information required by *blood transfusion adverse reaction report form*



- (a) date of birth, sex and identification code of the patient transfused;
- (b) number of the units and identification numbers of the blood components involved in the adverse event;
- (c) description of the type of blood component, duration of storage of the blood component prior to its transfusion;
- (d) patient signs and symptoms and laboratory findings;
- (e) severity of the event,
- (f) imputability, that is, the relation between the unfavorable effects observed and the blood component transfused, using a rating scale.





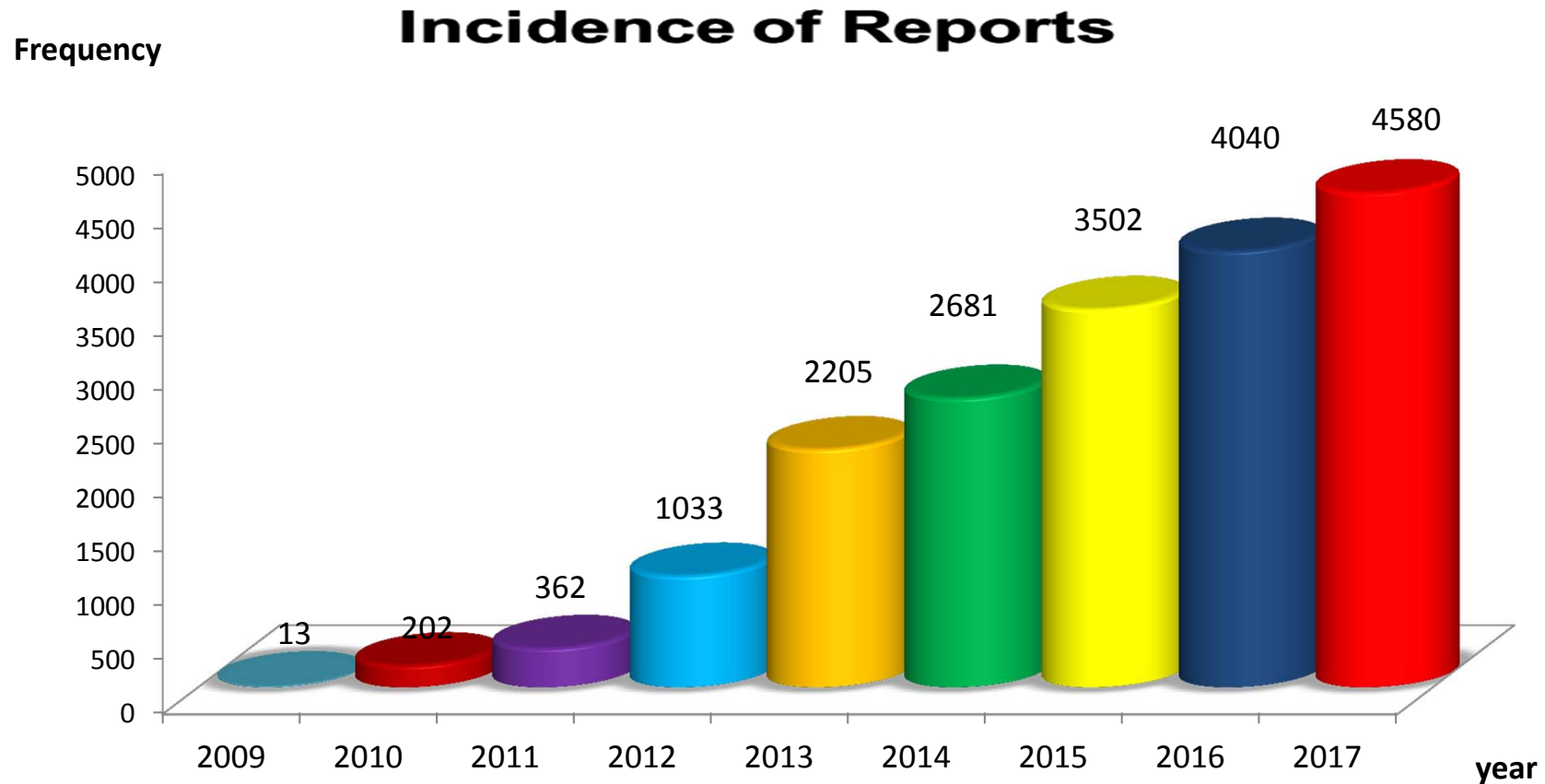


# Findings

- A total of 18618 of transfusion reactions were reported. Most complications were reported from Tehran Province 2647 (14.2%), and lowest from North Khorasan province, 3 (0.2%).
- The rates of reports in these years have increased.



# trend in adverse transfusion reactions (ATR) from 2009-2017.

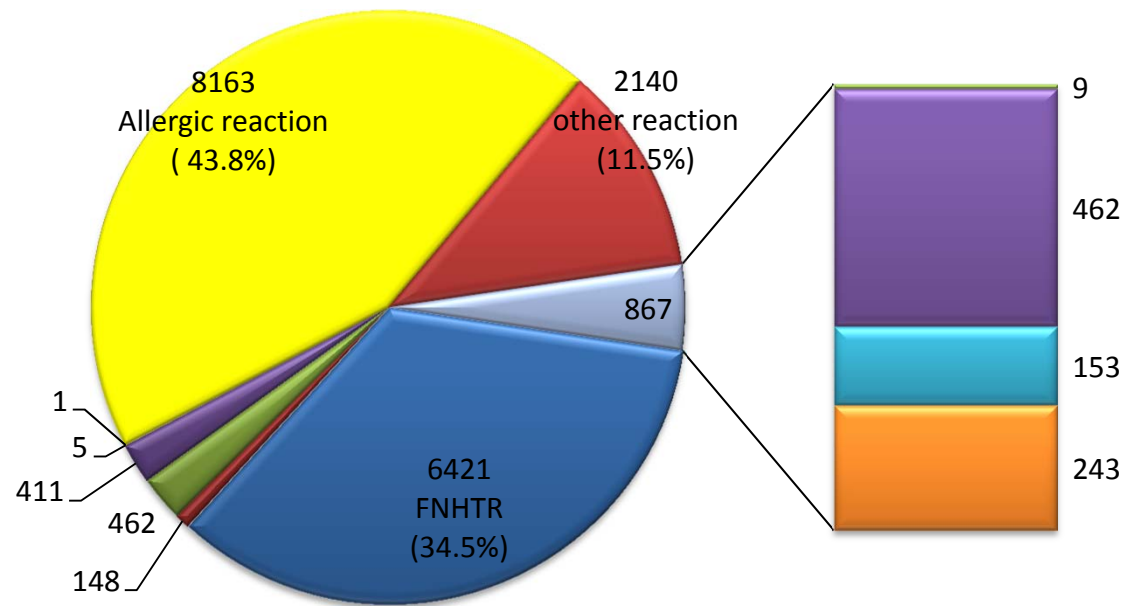




## incidence of ATR

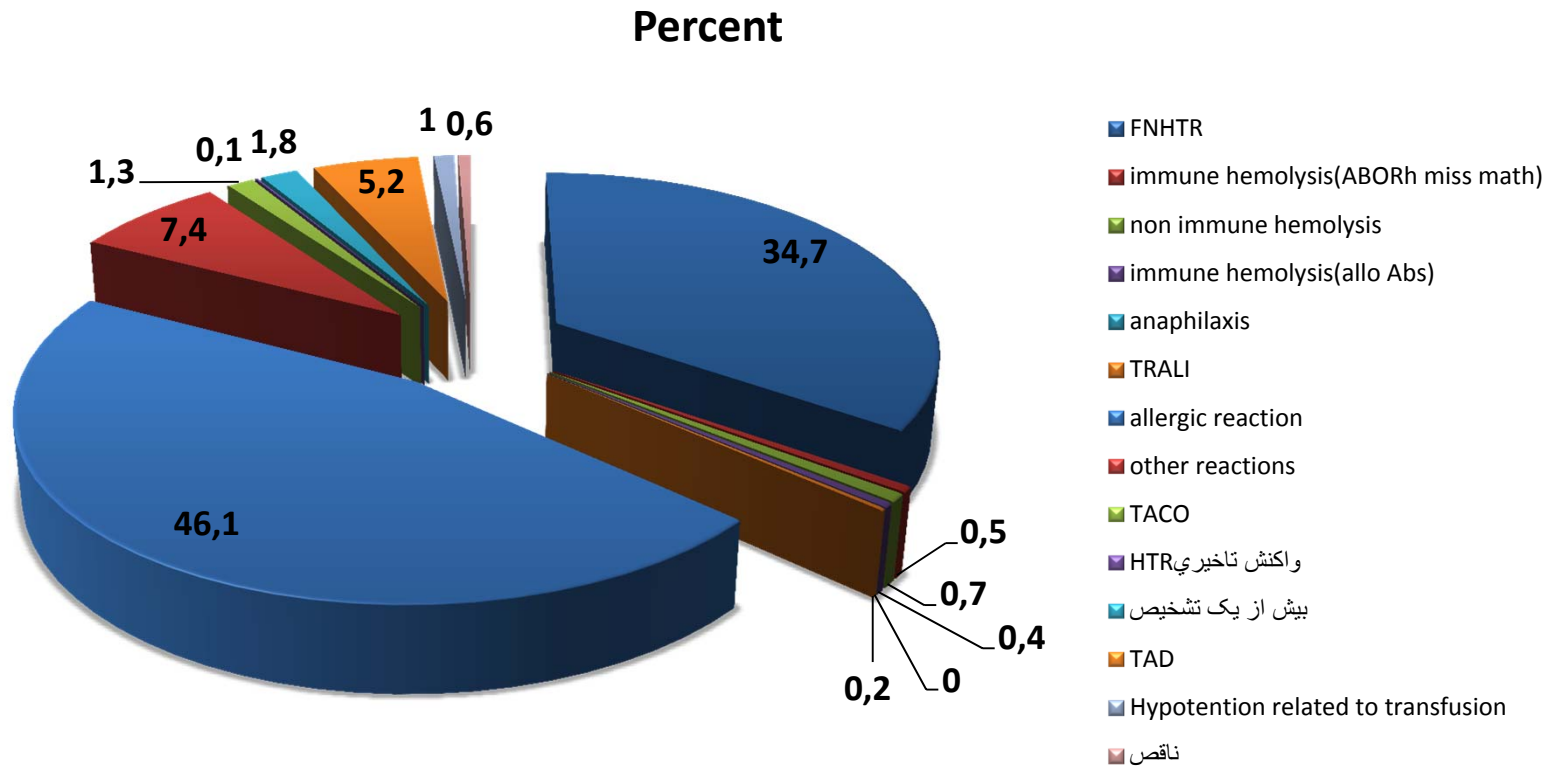
- The incidence of ATR was equivalent to **1.41 reactions per 1,000** units of blood components distributed.
- The majority of reported reactions (n=18610 or 99.99%), were acute or immediate and 8 (0.1%) considered as delayed blood transfusion reactions.
- As regards the type of reaction, **43.8% were of an allergic** nature and **34.5% of a febrile type**. There were no reports of Post Transfusion Purpura.

# Incidence of Reactions (2009- MARCH 2018)



- FNHTR
- immune hemolysis(ABORh miss math)
- Non immune Hemolysis
- Immune Hemolysis(alloab)
- bacterial infection
- GVHD
- Allergic reaction
- other reaction
- TRALI
- TACO
- Hypotention related to transfusion
- TAD

# Incidence of Reactions (2009- MARCH 2019)





# Transfusion errors

- Erroneous transfusions were classified into three categories: First type were due to **blood bank staff mistakes**, second type due to **nurse's errors** and the last ones, and were those happened as a result of mainly blood bank errors that could be easily identified by the nurses, if they paid enough attention. (**both blood bank staff and nurses mistakes**)



# Transfusion errors

- All erroneous administrations were due to human error; 74 cases (47.1%) happened at the patient's bedside. 54 cases (34.3%) were caused by blood bank errors and 29 cases (18.4%) were related to both blood bank and non-blood bank errors.



## The number of reported transfusion reactions by components

- The number of reported transfusion reactions following
- **Red Blood Cell** usage were 15619 (83.9%)
- **platelet** 1532 (8.2%)
- **Fresh Frozen Plasma** 1405 (7.5%)
- **Whole Blood** 56 (0.3%).





# Severity and mortality

- 11563(62.1%) cases of patients who have suffered complications had a history of blood transfusion.
- Regarding the severity of the reactions, in 16929 patients (90.9%), symptoms were mild and the majority of patients fully recovered, followed by 132 (0.7%) life threatening reactions and in 15 (0.1%) death has occurred.
- In complications leading to death(44), Transfusion was reason in 4 cases, Underlying disease in 26 cases, and 14 cases was due to both causes.

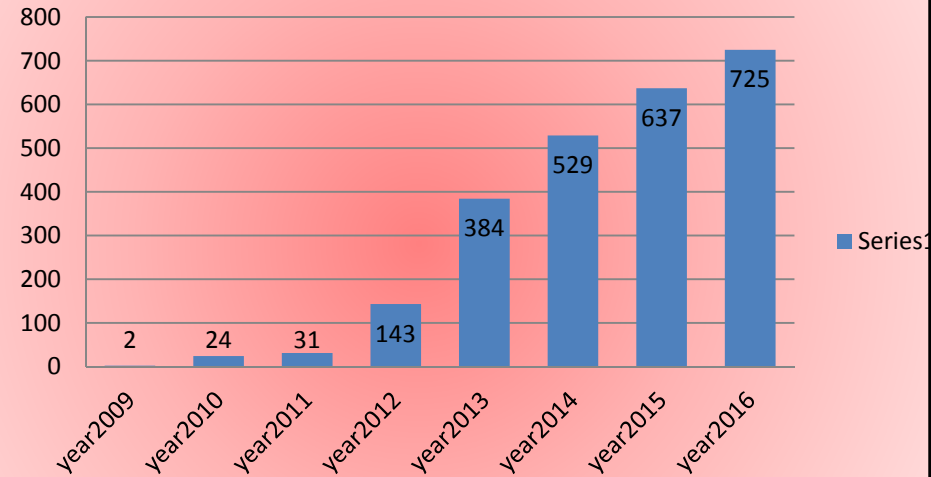


# Iranian National Hemovigilance System (INHS)



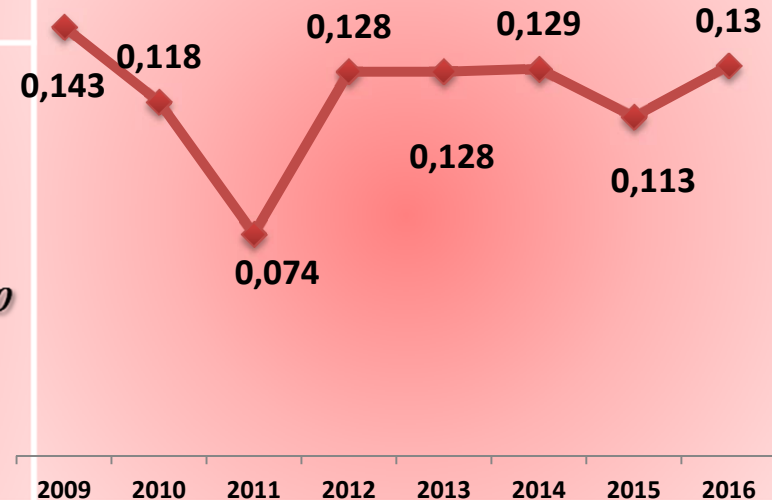
## 1 INHS Index

$$\frac{\text{number of hospitals with hemovigilance system}}{\text{total hospitals}} \times 100$$



## 2 INHS Index

$$\frac{\text{number of transfusion adverse reactions in hospitals with hemovigilance system}}{\text{number of blood blood component issued to hospitals with hemovigilance system}} \times 100$$





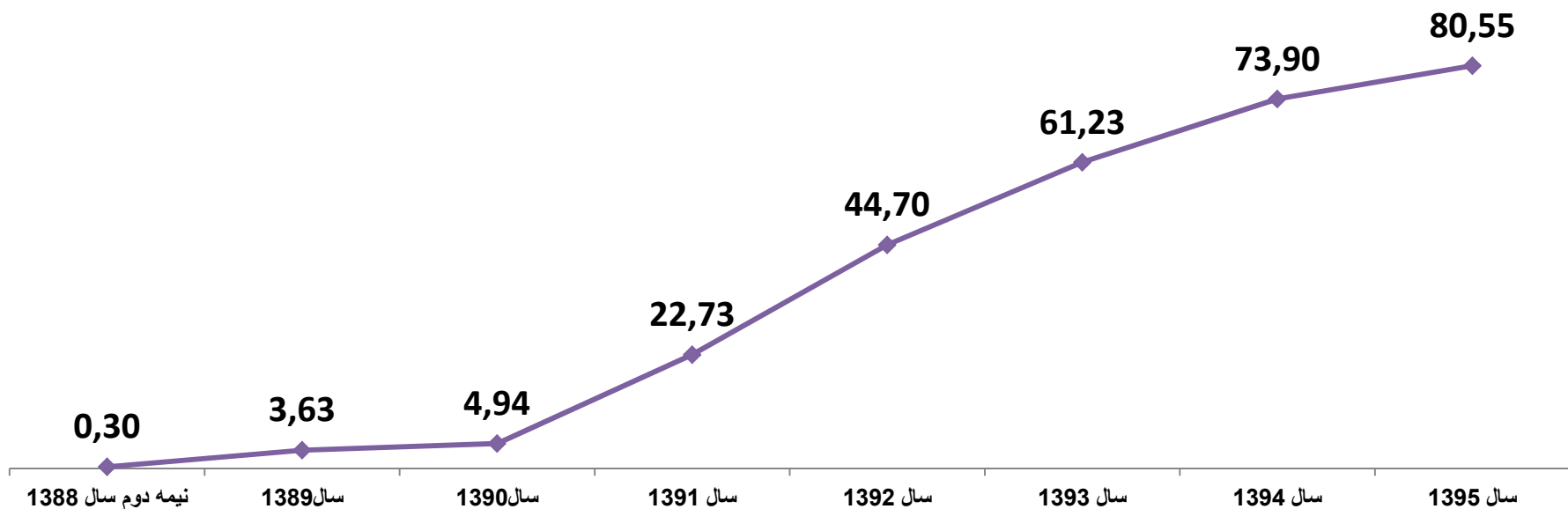
# Iranian National Hemovigilance System (INHS)



## 1 INHS Index

$$\frac{\text{number of hospitals with hemovigilance system}}{\text{total hospitals}} \times 100$$

year	with system	hospitals	index
2009	2	674	0.30
2010	24	662	3.63
2011	31	627	4.94
2012	143	629	22.73
2013	384	859	44.70
2014	529	864	61.23
2015	637	862	73.90
2016	725	900	80.55



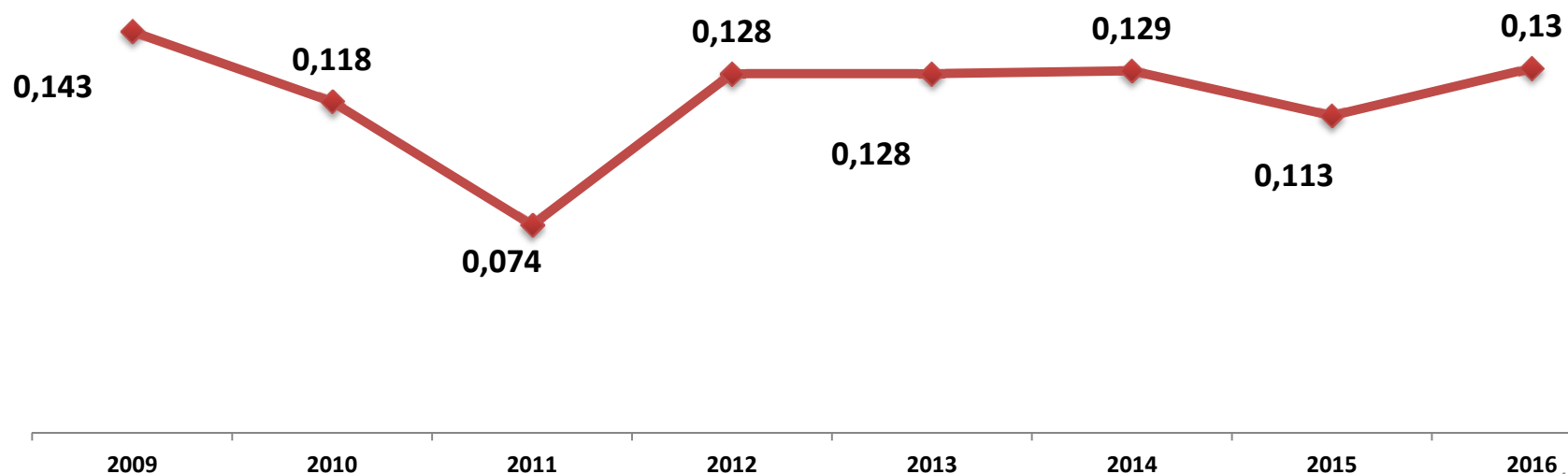
# Iranian National Hemovigilance System (INHS)

2

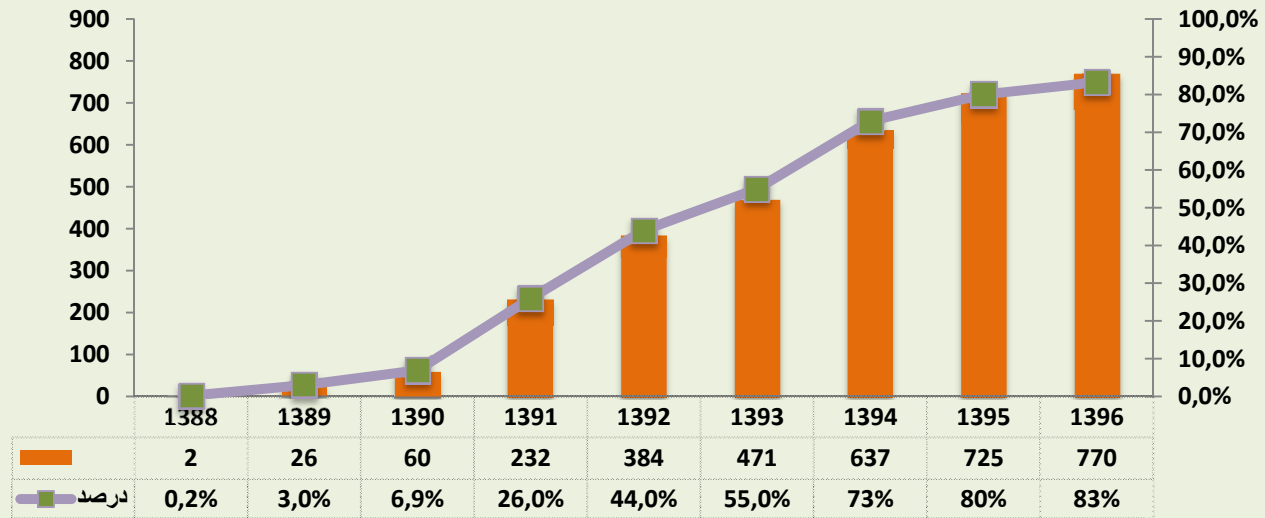
## INHS Index

*number of transfusion adverse reactions  
in hospitals with hemovigilance system*  
 $\frac{\text{number of transfusion adverse reactions in hospitals with hemovigilance system}}{\text{number of blood blood component issued to hospitals with hemovigilance system}} \times 100$

year	No. Adverse reactions	No. issued	index
2009	13	9084	0.143
2010	186	157412	0.118
2011	352	474741	0.074
2012	1011	792833	0.128
2013	2123	1654941	0.128
2014	2612	2017250	0.129
2015	3421	3032661	0.113
2016	4039	3092493	0.130



تعداد و درصد بیمارستانهای دارای سیستم هموویژلانس به تفکیک سال





## OUR MAJOR PROBLEMS

- 1-Some **transfusion committee** are not active. (For example the hospital has HTC but isn't in standard manner)
- 2-The physicians and nurses don't pass **transfusion course** in the universities
- 3-There isn't **transfusion specialist** in hospital as transfusion consultant
- 4-There isn't **Transfusion fellowship** for physician in Iran yet

# Weaknesses -1

- No transfusion speciality or fellowship course in the country
- Most of transfusion committees don,t work efficiently.
- There is not any transfusion courses for nurses, general physicians, midwives and ...during their education.
- Lack of enough support from MOH
- There is not any ISBT approved software for blood banking and haemovigilance reporting.



## Weaknesses-2

### There are some difficulties in purchasing the validated software:

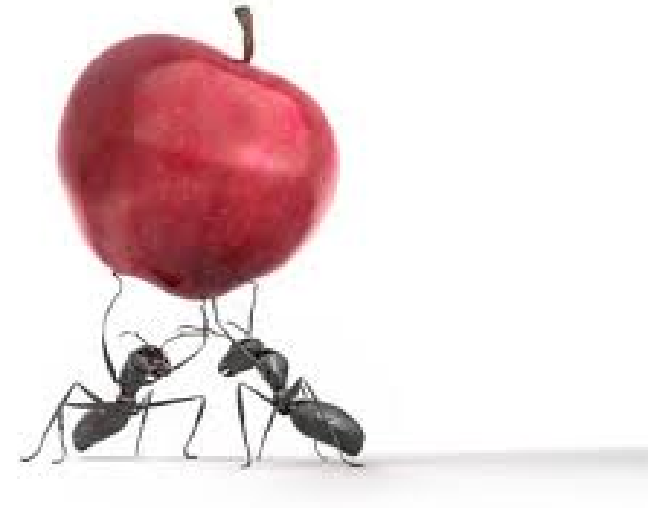
- The Expense: it is on priority for neither MOH nor hospitals to designate some budget for purchasing these software.
- There is some strategic limitations for us to purchase or import the software and devices.





# Strengths

- No punishment culture
- A centralised organisation
- IBTO is WHO Collaborator in Eastern Mediterranean region for 4 years.
- A great enthusiasm to achieve our goals



# HAEMOVIGILANCE

مهمترین چالشهای پیش رودر برقراری  
سیستم هموویژلانس



## " کند بودن روند استقرار سیستم هموویتز لانس در مراکز درمانی "

### اقدامات اصلاحی پیشنهادی:

1. آموزش کلیه پرسنل بیمارستان توسط هسته آموزشی همان بیمارستان یا شرکت پرسنل در سمینارها
2. بهره گیری از روش آموزش های غیر حضوری
3. تهیه مولتی مدیای مناسب برای آموزش مخاطبین با همکاری وزارت بهداشت
4. نظارت مستمر و دقیق معاونت درمان دانشگاههای علوم پزشکی و الزام آنان در این راستا
5. تبیین آموزش های هموویتز لانس در آموزش های آکادمیک ومدون گروه های پزشکی ، پرستاری و علوم آزمایشگاهی
6. الزام در گذراندن دوره های بازآموزی هموویتز لانس برای گروه های فوق

## "عدم گزارش وقوع تمام موارد عارضه"

### علل:

1. کمبود نیروی انسانی (خصوصاً پرستار) در بیمارستانها
2. کمبود نیروی انسانی در پایگاههای انتقال خون
3. وقت گیر بودن ارجاع دستی فرمهای گزارش عوارض

### اقدامات اصلاحی پیشنهادی:

1. تامین نیروی انسانی
  2. تبیین ردیف شغلی ( پرستار ارشد هموویتالانس )
  3. تسریع در تهیه نرم افزار هموویتالانس یا الزام HIS بیمارستان ها به ایجاد ماژول بانک خون و هموویتالانس
- ( لازم به ذکر است که کلیه اطلاعات لازم برای تهیه این نرم افزار یا ماژول در سال ۱۳۹۱ به دفتر فناوری وزارت بهداشت ، درمان و آموزش تحویل داده شده و علیرغم شروع اقدامات ، تهیه آن هنوز به نتیجه نرسیده است.)

محاسبه شیوع عوارض بر حسب مصرف فرآورده ها امکان پذیر نمی باشد

**علل:**

بیمارستان ها به جهت کمبود نیروی انسانی در تهیه آمار مربوطه اهمال می ورزند.

**اقدام اصلاحی پیشنهادی:**

تسریع در تهیه نرم افزار هموویژلانس یا الزام HIS بیمارستان ها به ایجاد ماژول بانک خون و هموویژلانس

با توجه به عدم وجود نرم افزار مربوطه امکان بررسی اندیکاسیون های تزریق خون در مراکز درمانی توسط سازمان انتقال خون میسر نمی باشد. همچنین در مراکز درمانی اندیکاسیون ها به صورت جدی کنترل نمی گردد.

#### اقدام اصلاحی پیشنهادی:

تسریع در تهیه نرم افزار هموویژلانس یا الزام HIS بیمارستان ها به ایجاد ماژول بانک خون و هموویژلانس

همکاری لازم از طرف پزشکان ارشد هموویتزانس و مسئولین بیمارستان ها با واحد هموویتزانس سازمان انتقال خون صورت نمی پذیرد.

#### اقدامات اصلاحی پیشنهادی:

1. بهره گیری از گزینه های تشویقی جهت پرسنل مرتبط در امر هموویتزانس از قبیل مصادیق اضافه کار ، پاداش و....
2. تبیین ردیف پزشک ارشد هموویتزانس در چارت تشکیلات مراکز درمانی



# ACKNOWLEDGMENTS



- I thank the all hospitals staff for establishing haemovigilance system and great cooperating in improving patient blood safety in Iran.



# HAEMOVIGILANCE



