

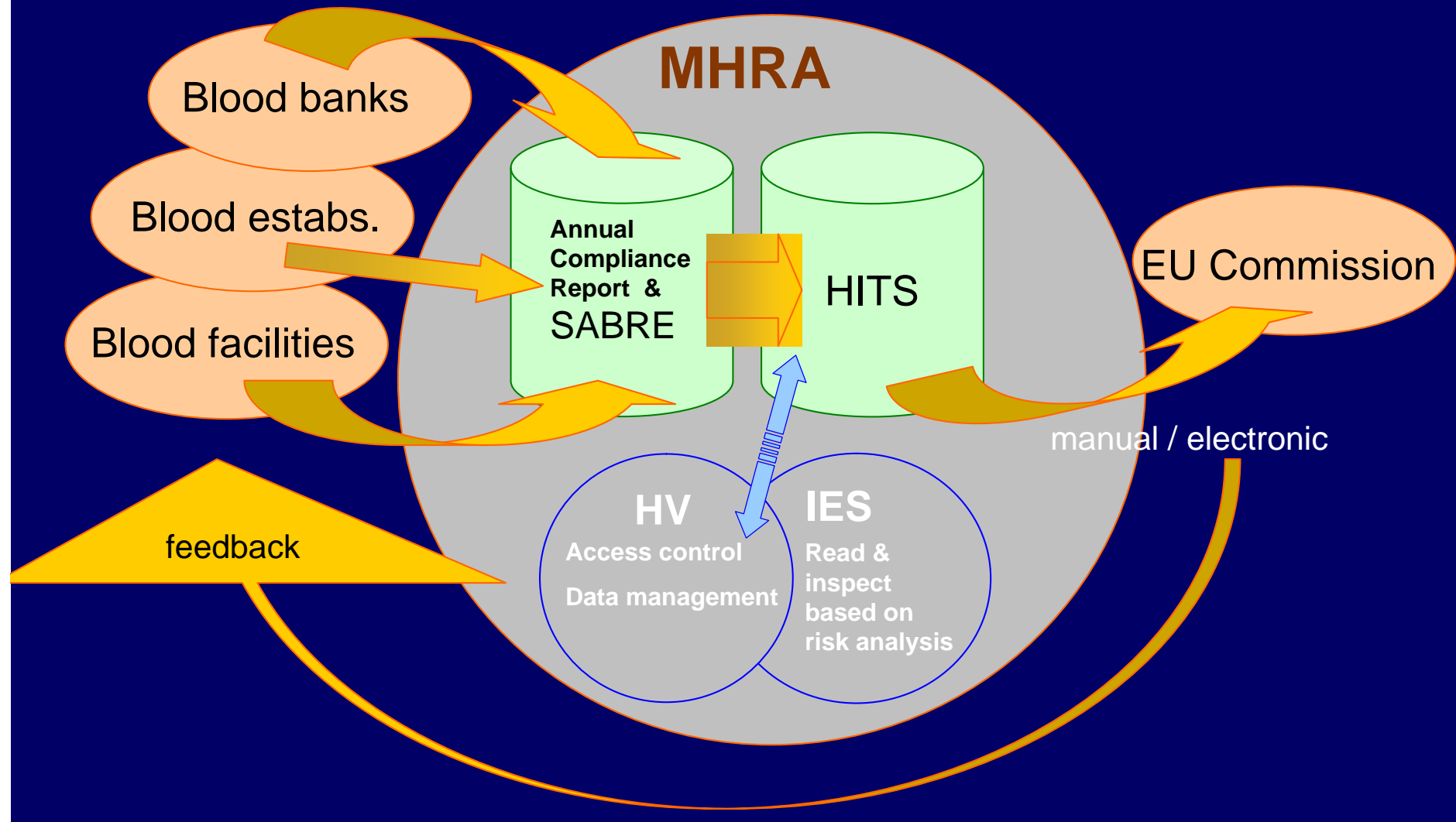
REGULATORY HAEMOVIGILANCE: Serious Adverse Reactions

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- Haemovigilance data 2005 - 2011 – UK
- Serious Adverse Reactions 2012
- Reporting trends for the London Region

Safeguarding public health

UK Blood Safety & Quality Regulation + haemovigilance:

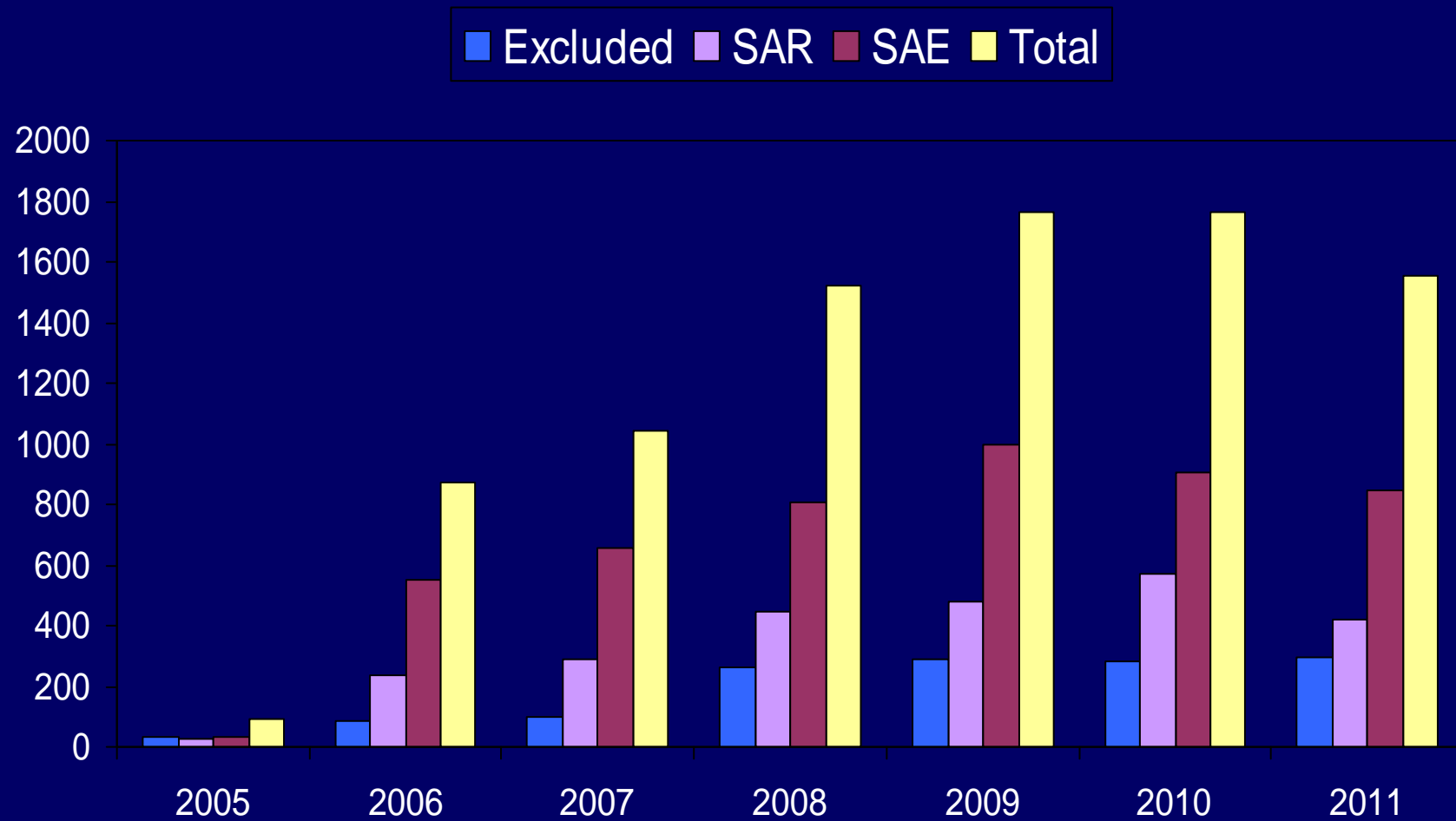


- Provision of system for collection of SAEs & SARs
- Annual summary reports
 - UK reporters
 - EU Commission/working groups
- Review of all reports
 - adequacy / quality
 - timeliness
 - reconciliation with SHOT data
- Liaison with inspectors
 - non-reporters
 - high risk reporters (late, high / low, repeat)
 - exceptions

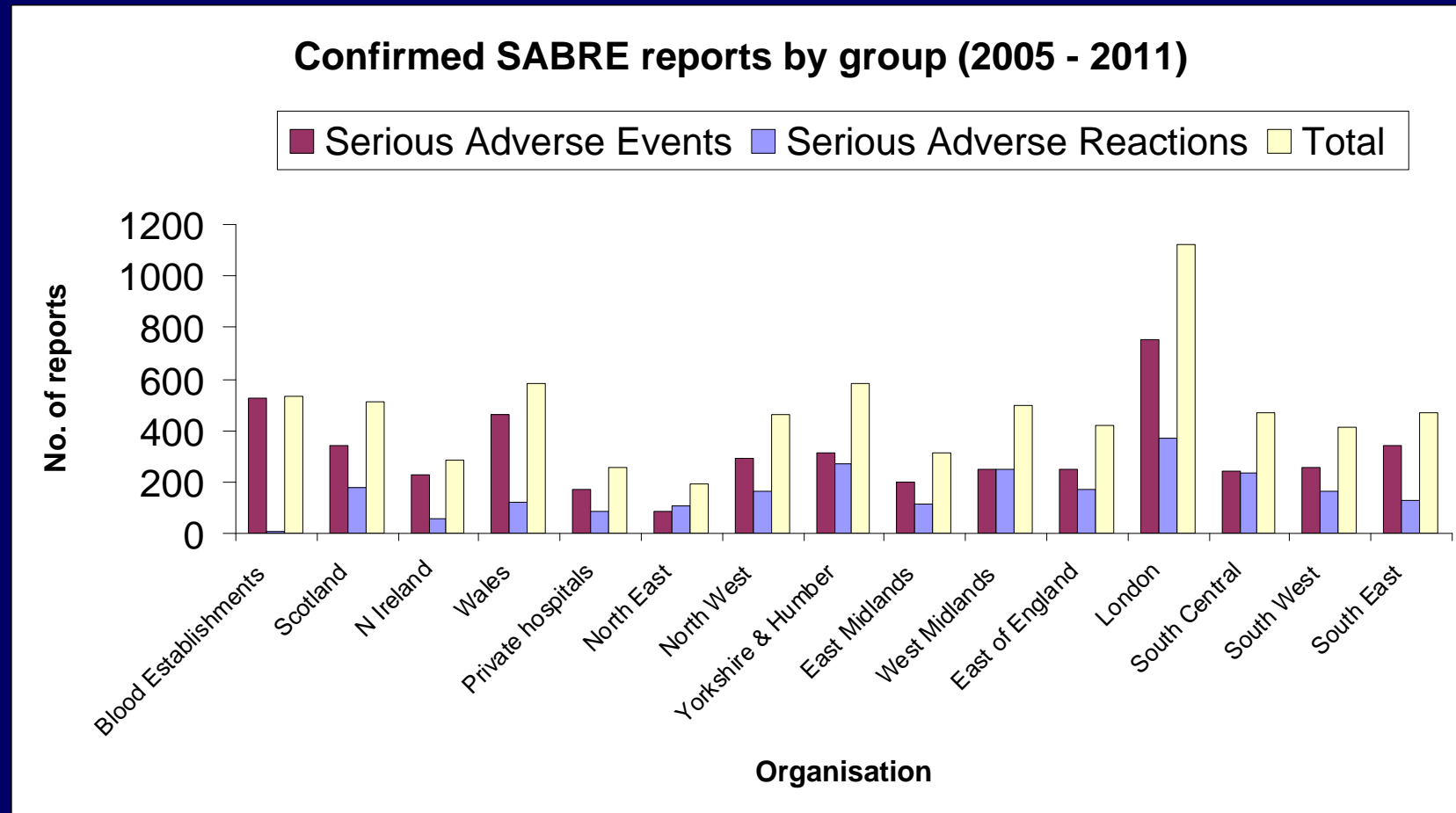
All UK SABRE reports submitted 2005 – 2011:

- Serious Adverse Events = 5936
- Serious Adverse Reactions = 2668
- Total = 8604
- Excluded reports = 1332
(did not meet EU reporting guidelines)

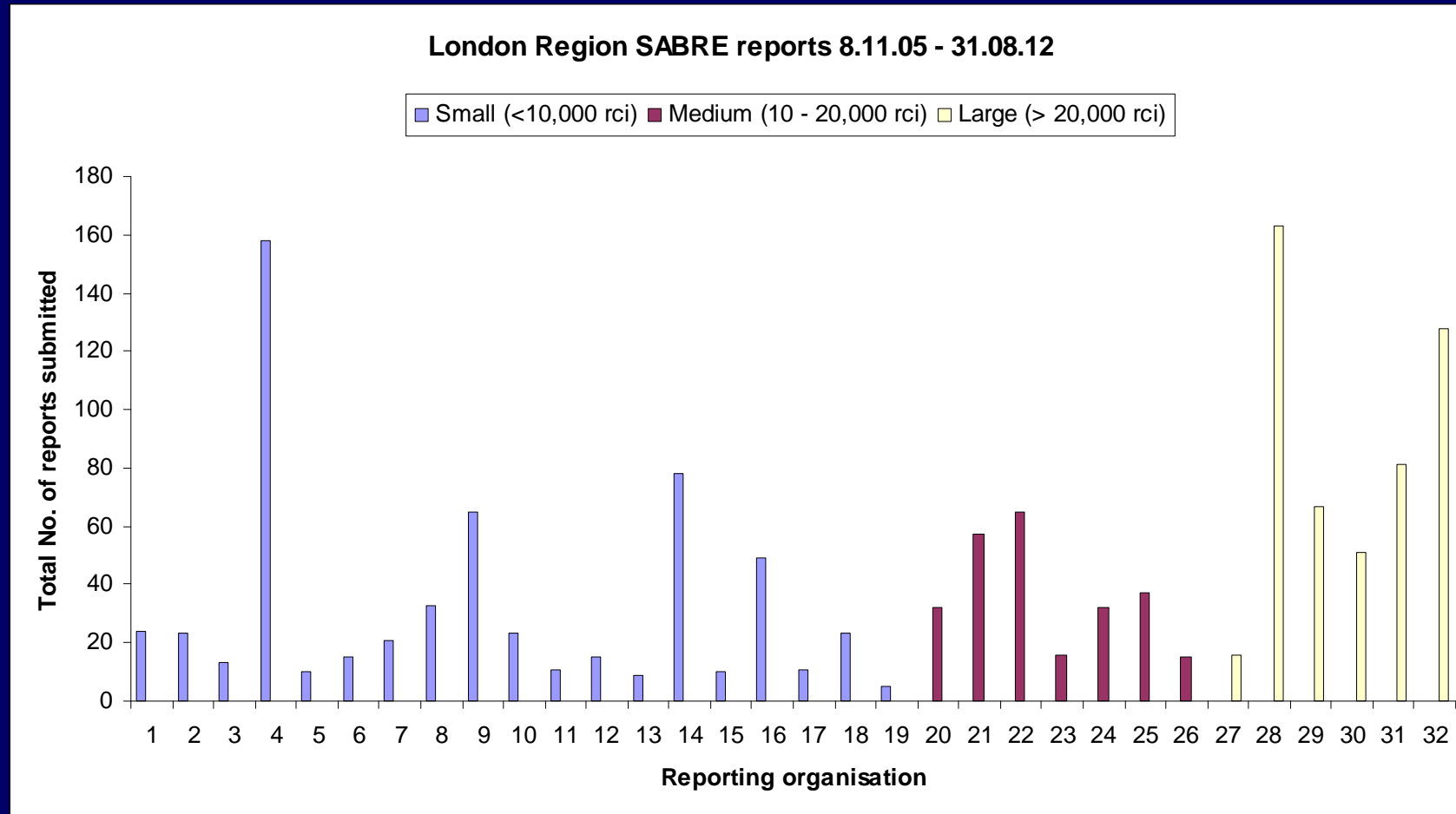
All UK SABRE reports by year



All UK SABRE reports (2005 – 2011) by RTC region



SABRE reporting levels in the London RTC Region



UK Serious Adverse Reactions 2011 (confirmed n = 444)

REACTION TYPE	No. of reports (all imputability levels)	No of reports where imputability ≥ 2	DEATHS
Anaphylaxis / hypersensitivity	186	98	1 (IL2)
Other	176	60	
TRALI	28	3	3
Immunological haemolysis due to other allo-antibody	26	14	
Transfusion transmitted bacterial infection	16	0	
Immunological haemolysis due to ABO incompatibility	3	1	1 (IL1)
Transfusion transmitted viral infection (HBV)	1	0	
Transfusion transmitted viral infection (HCV)	3	0	
Transfusion transmitted viral infection (HIV-1/2)	1	0	
Post transfusion purpura	3	1	
Non- immunological haemolysis	1	1	

Serious Adverse Reactions – Deaths 2011

- Total No. of deaths reported in 2011 = 5
- No. of deaths where imputability level ≥ 2 = 2
- Case 1 = TRALI
(pending Coroner's report, BE report = NOT TRALI)
- Case 2 = Anaphylaxis/hypersensitivity

UK Serious Adverse Reactions 2011

- Reaction type 'Other' = 176 reports

FNHTR = 127

TACO = 33

TAD = 6

NFNHTR = 5

Other = 5

SABRE reports 2012 (unverified)

01.01.12 – 30.09.12

Incident Type	Notification	Confirmation	Exclusion	Total
Serious Adverse Event	130	582	98	810
Serious adverse Reaction	34	248	35	317
Grand Total	164	830	133	1127

Unverified UK SAR reports - 01.01.2012 – 30.09.2012 (n = 248)

REACTION TYPE	No. of reports (all imputability levels)	No of reports where imputability ≥ 2
Anaphylaxis / hypersensitivity	88	52
Other (FNHTR/ TACO/ TAD)	85	27
Immunological haemolysis due to other allo-antibody	31	24
TRALI	21	8
Transfusion transmitted bacterial infection	15	1
Immunological haemolysis due to ABO incompatibility	2	2
Transfusion transmitted viral infection (HBV)	4	3
Non-immunological haemolysis	1	1
Post- transfusion purpura	1	1

London RTC Region Serious Adverse Reactions

Confirmed reports 01.01.12 – 30.09.12 (n = 36)

REACTION TYPE	No. of reports (all imputability levels)	No of reports where imputability ≥ 2
Anaphylaxis / hypersensitivity	14	10
Other (FNHTR/ TACO/ TAD)	9	4
Immunological haemolysis due to other allo-antibody	6	3
TRALI	3	0
Transfusion transmitted bacterial infection	3	0
Post transfusion purpura	1	0

Safeguarding public health

Serious Adverse Reactions

Hyperhaemolysis:

10 reports since 2005

7 have been reported by London region hospitals

Thank you !