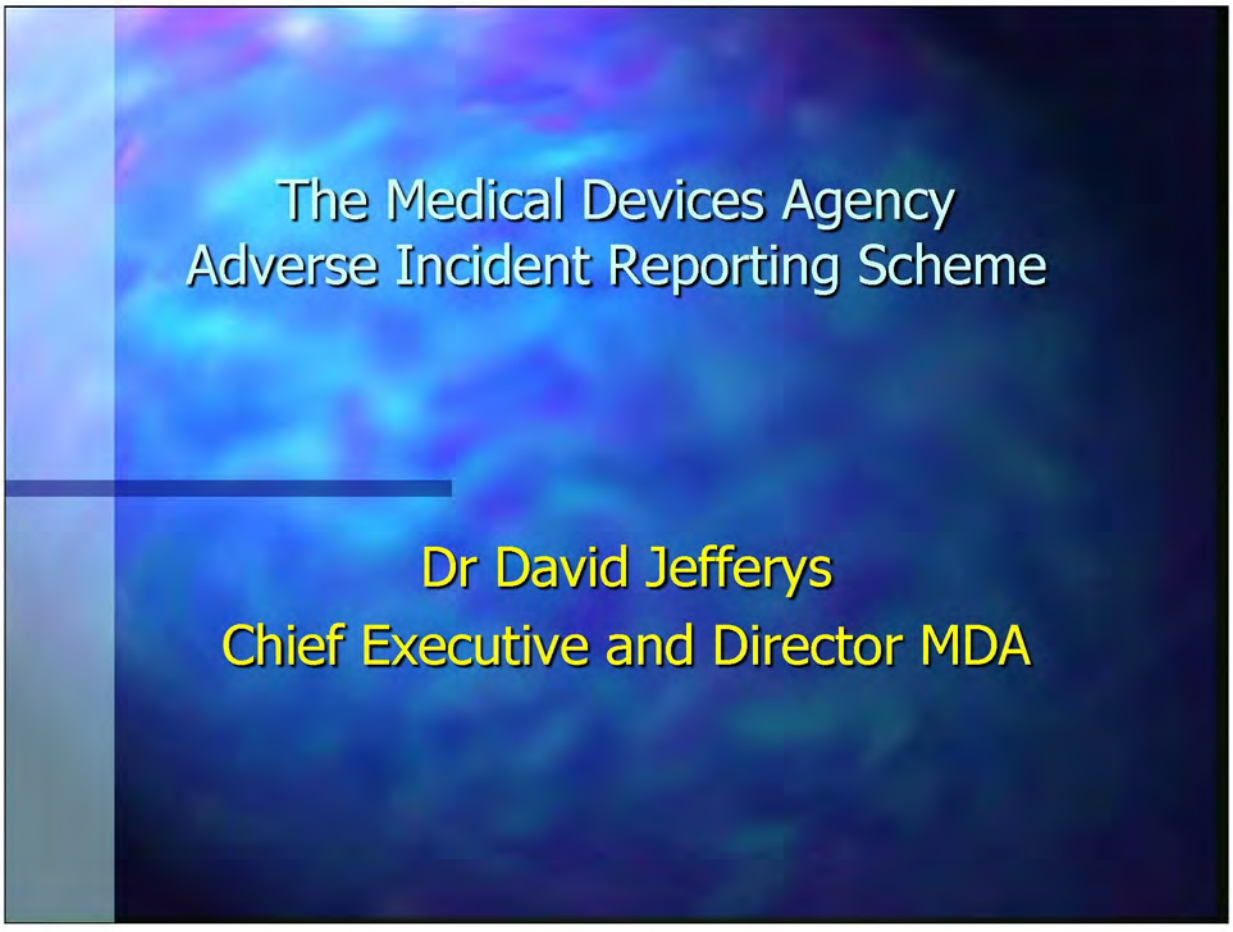

The Medical Devices Agency
Adverse Incident Reporting Scheme
Dr David Jefferys
Chief Executive and Director MDA

The Medical Devices Sector

Medical devices play a vital role in all aspects of health and community care

- around 20,000 devices on the UK market
- more than 36 million people in the UK use a medical device each day
- Medical Devices are becoming increasingly complex and sophisticated
- Technology transfer to primary and community care
- expanding OTC market and patient use
- Global Industry - EU and Global Dimensions

The UK/MDA Reporting Schemes

- Medical Device Adverse Incident User Reporting Scheme
- Mandatory Manufacturer Vigilance Reporting Scheme
- The User reporting scheme
  - first system world-wide introduced in 1960's
  - largest and most comprehensive user system world-wide
  - notable world-wide first detections

The Development of the System

- Supported by the Adverse Incident Tracking System AITC
- electronic (web-based) reporting for all users
- patient and lay user reporting
- trend analysis
- International Vigilance exchange
- European database

The System Today

- Largest user reporting scheme world wide
- source of 60% of the total Vigilance reports exchanged in the EU
- receives > 8,000 reports per annum

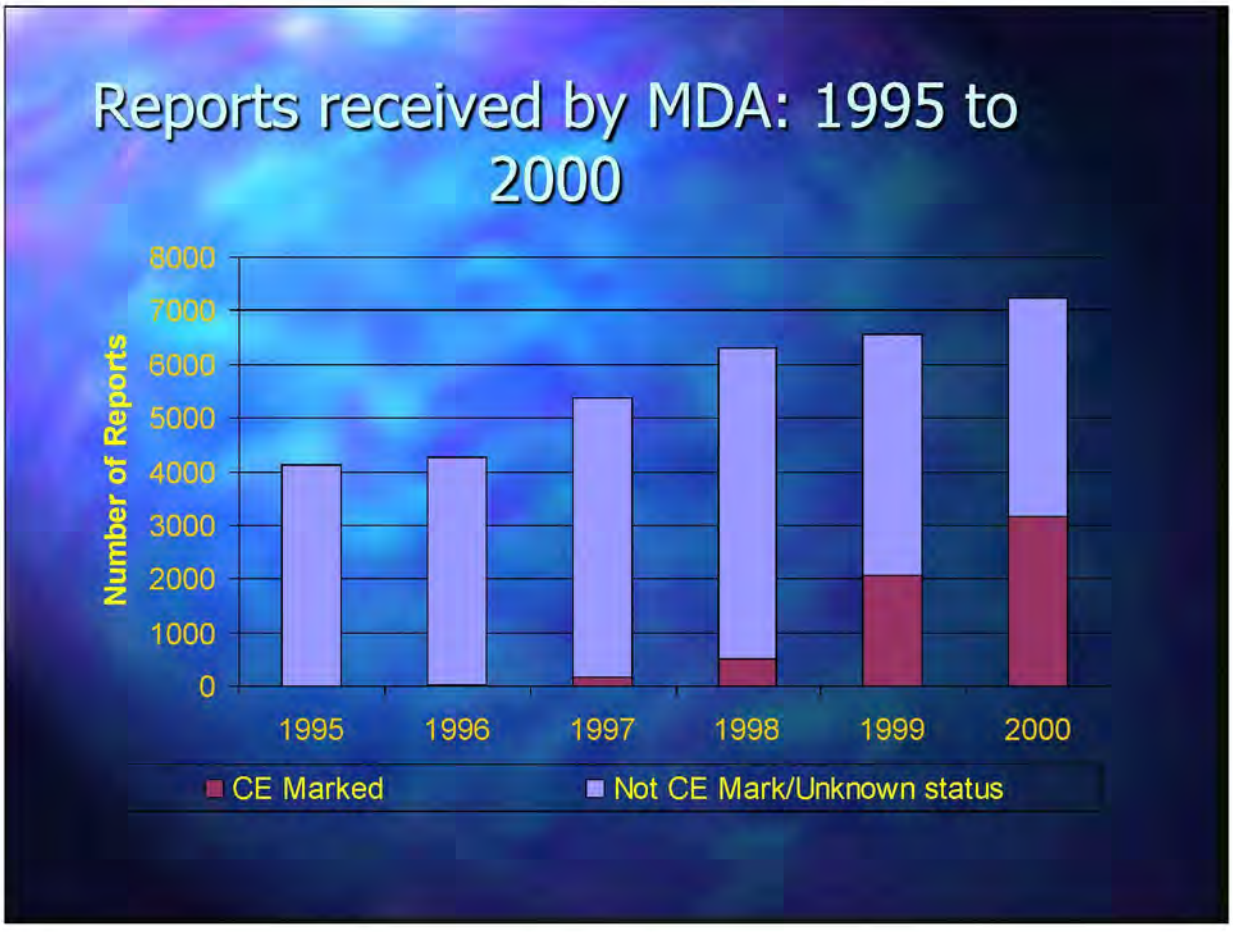
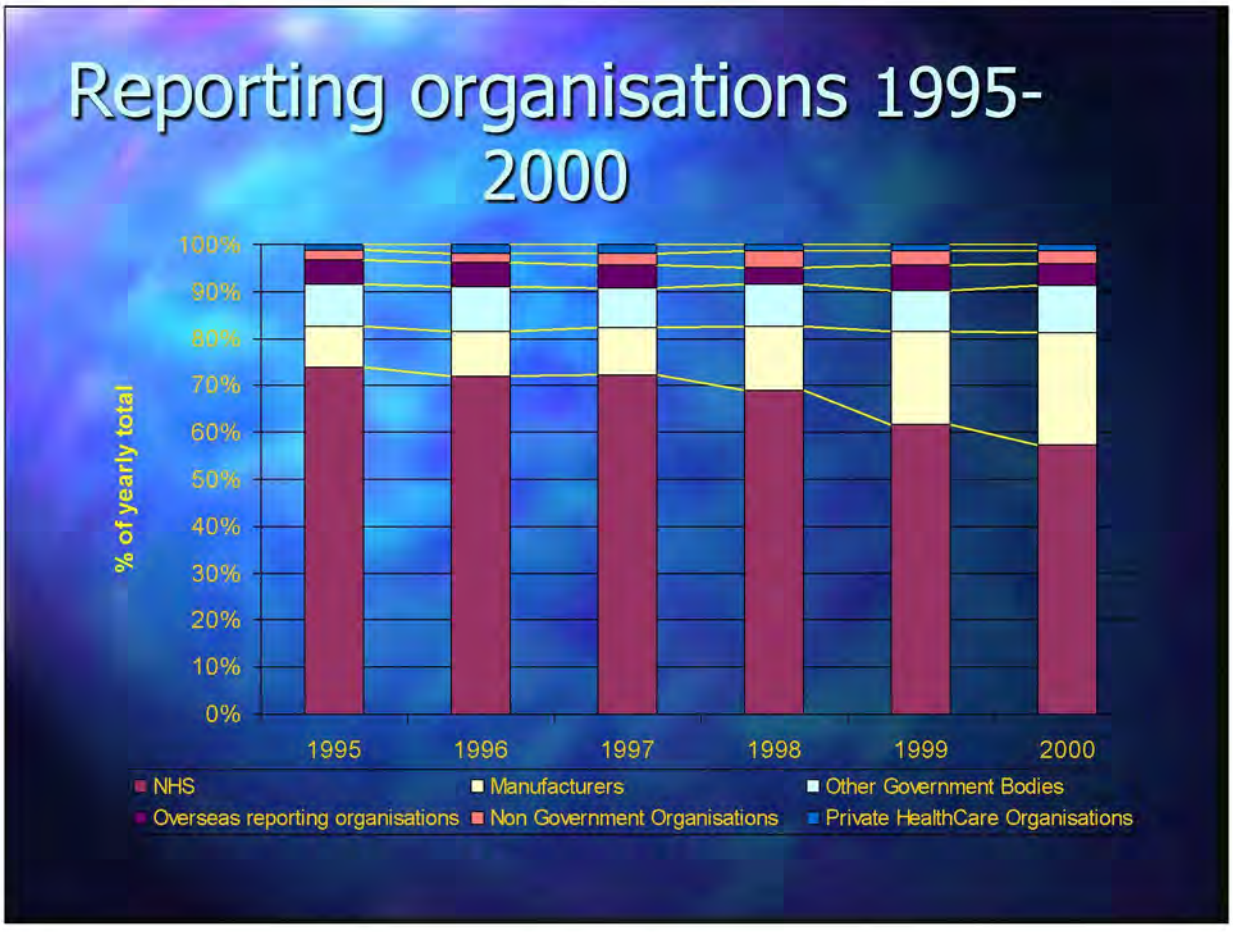


Chart shows growth of reports from all sources over the last 6 years:
those from users under the voluntary reporting scheme those from manufacturers reported under the mandatory vigilance reporting scheme and& those organisations

We actually have data going back to the founding of NATRIC the precursor to AIC in 1988, before which there was no systematic data collection.
The Medical Device regulations first came onto the scene in the UK via the Consumer Protection Act in 1995 but it was not until the active implantable and general medical device directive transitional arrangements ended that you begin to see the effects of introducing CE marked products onto the European market.
From 1997 we began to see the first incidents trickling in involving CE marked product. Since then the number has grown significantly such that now 43% of reported incidents now involve CE marked products. Some aspects of post market surveillance are alive and well under the Directives but there is still room for improvement.

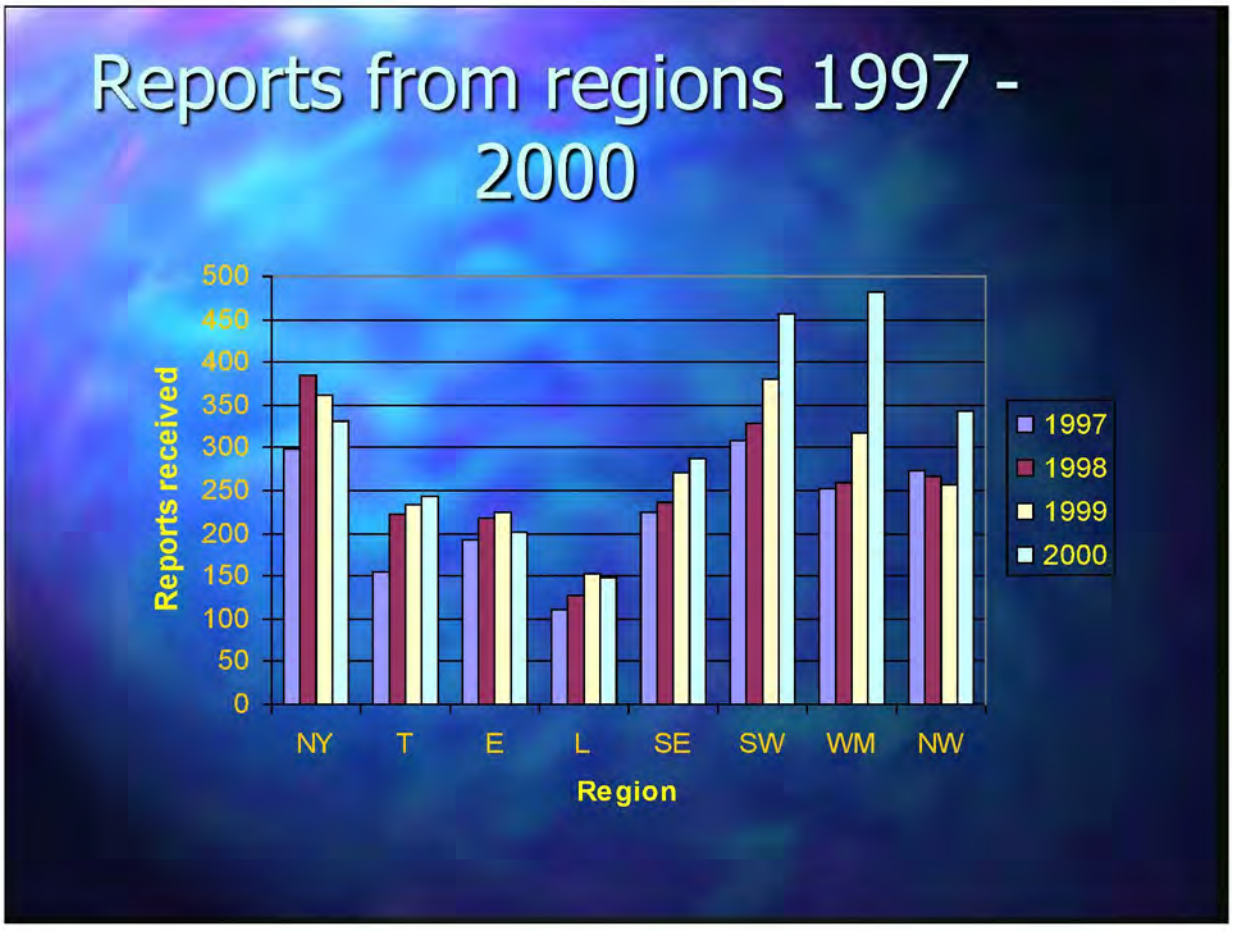
This slide suggests that the vigilance system in the UK has now reached some level of maturity.
You could argue that we seem to have a relatively well educated and on the whole responsible body of manufacturers who for the most part are aware of the mandatory reporting system. The number of reports that can be classified as Vigilance reports has now plateaued at around the 500 per year level. We could anticipate that this might increase slightly once the IVD Directive transition arrangements expire but not by a terrific amount. (next slide)



This slide reveals where our reports come from in percentage terms. The clear growth area is in the number of reports sent in by manufacturers. Only a third of these reports would be classed as vigilance cases revealing the large amount of cooperation afforded to MDA by manufacturers in sharing their non-vigilance incident data with us.

This is an encouraging trend. The data in the last two slides might suggest that the time is ripe for MDA to begin to explore with some manufacturers summary reporting for certain common and well-characterised adverse events. With the revised Vigilance guidelines now published this is an option that European CAs could adopt. However we would expect manufacturers to have robust trending procedures before MDA would consider this approach.

Indeed trending of events by manufacturers is now essential with the exemptions now brought into play through version 4 of the directives.



This slide reveals that the number of reports from the English regions continues to rise in response, we hope, to our initiatives to increase the number of Liaison officers in the English region. We now have a liaison officer appointed in every trust, health authority and social service department which we are very pleased with.

Adverse Incident Strategy

- Increase reporting rates
  - educational programme
  - identifying under-reporting
  - appointment of Liaison Officer in all Trusts, Health Authorities and Social Service Departments
  - extension of liaison officers to all PCTs

installation of a new adverse incident tracking system and database

electronic reporting of adverse incidents

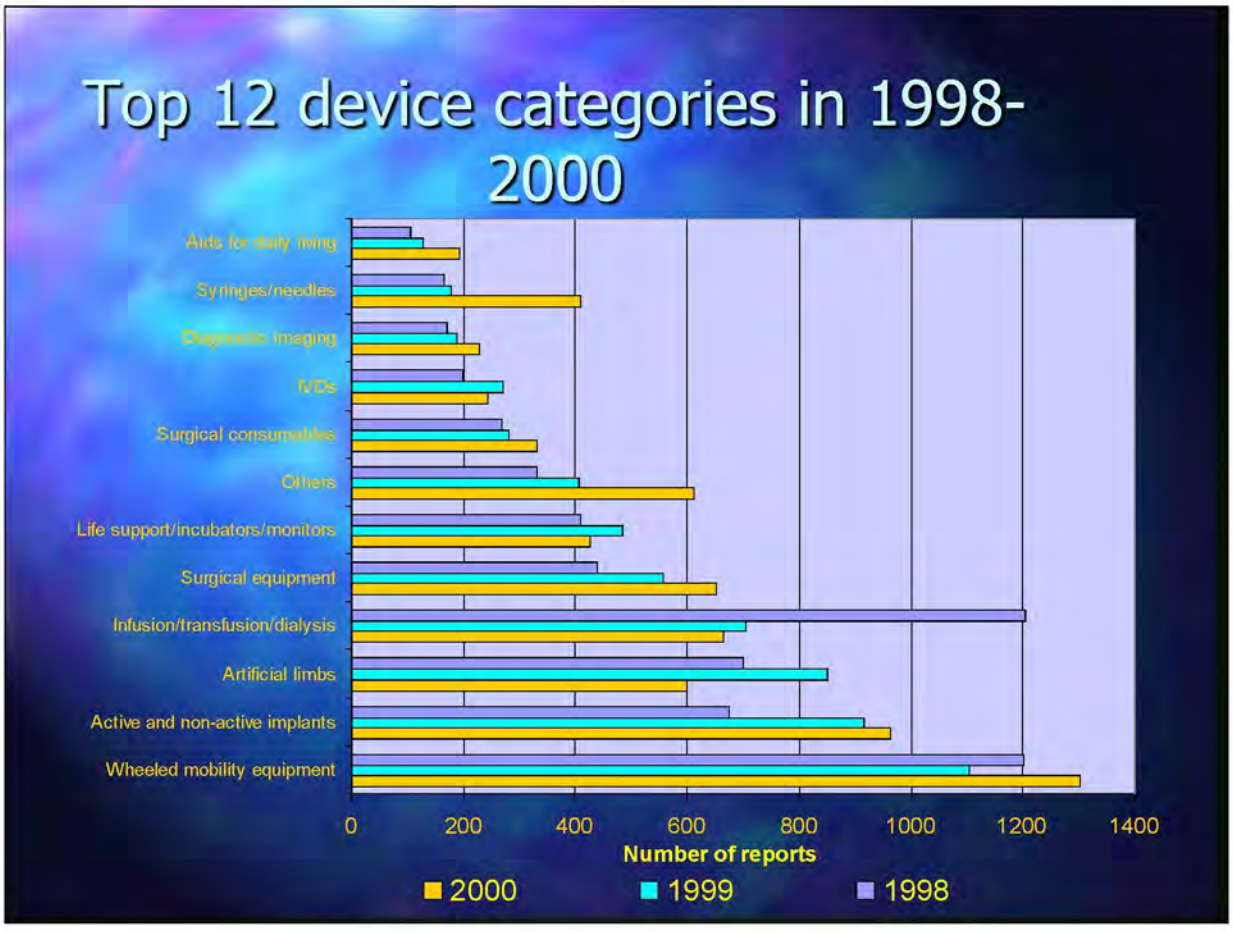
Adverse Incident Strategy

- Direct user reporting by the public
- International initiatives
  - global vigilance exchange
  - European exchange and database
- Benchmarking systems with MCA
- working with NPSA

Adverse Incident reports

Of the more significant reports we received

- 87 involved a fatality; and
- 558 involved serious injury.
- 1,632 merited in-depth investigations;
- 2,790 were investigated by manufacturers under MDA supervision;
- 406 were investigated by other organisations whose conclusions were fed to us; and
- 1389 did not need immediate action but helped to monitor trends and detect patterns

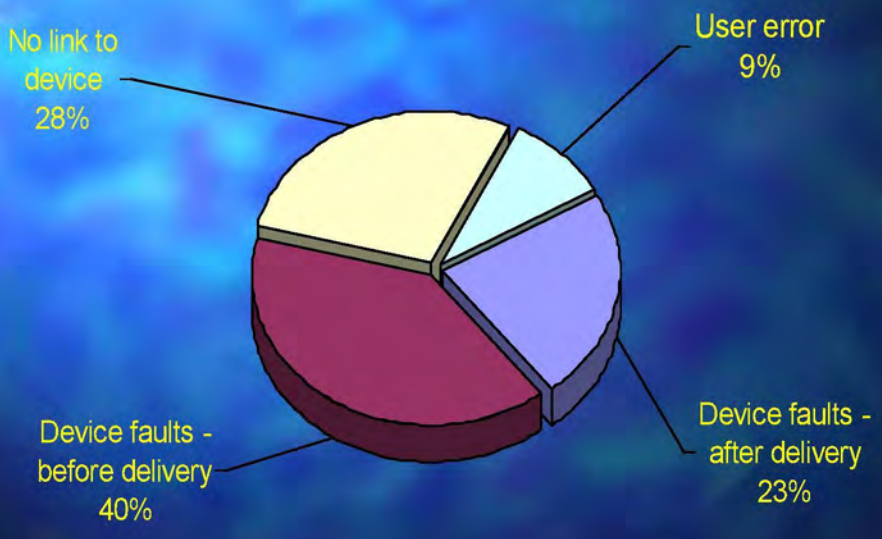


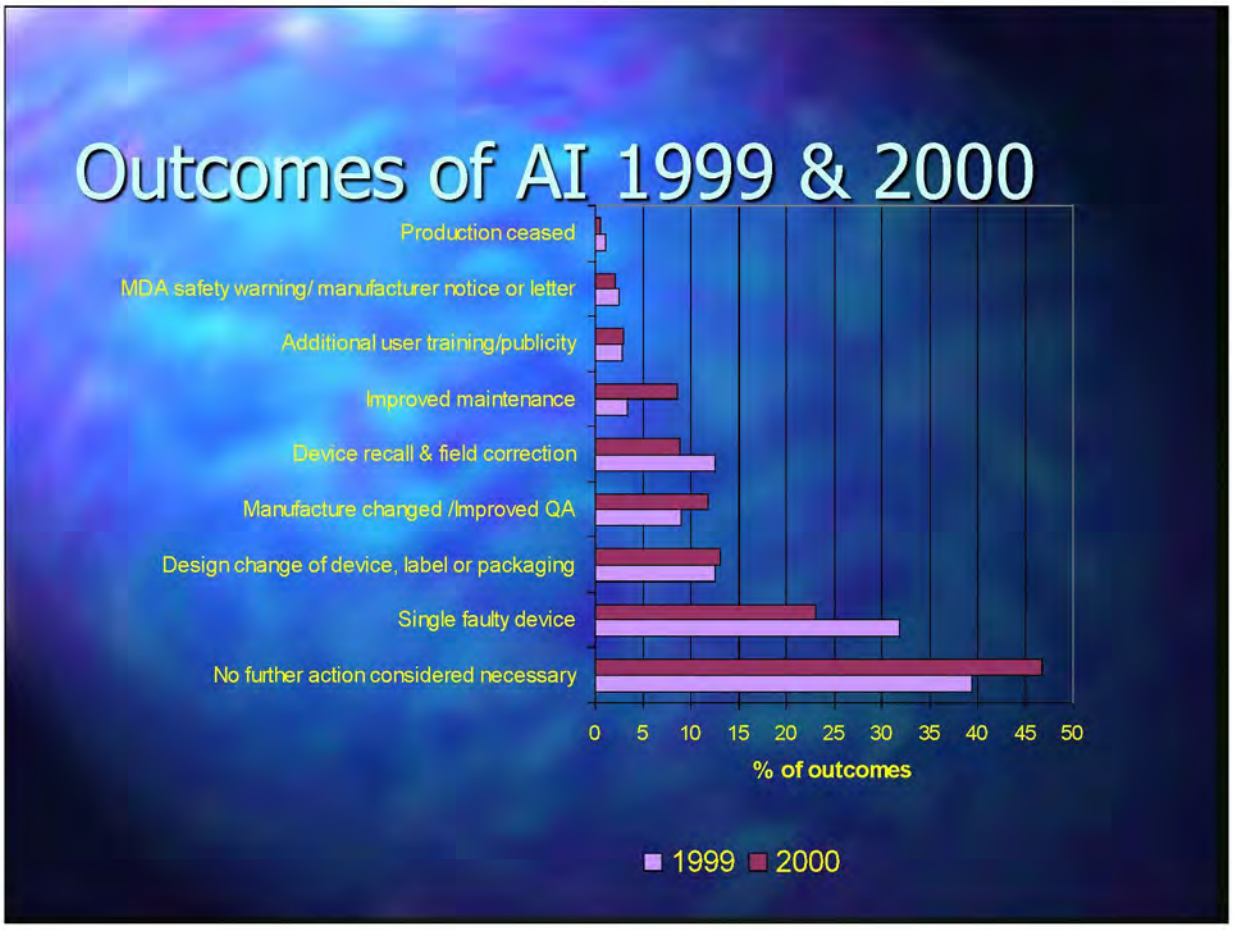
This slide shows a breakdown of the number of incident reports received for various categories of medical devices and equipment for the last three years.

As a result of investigations we:

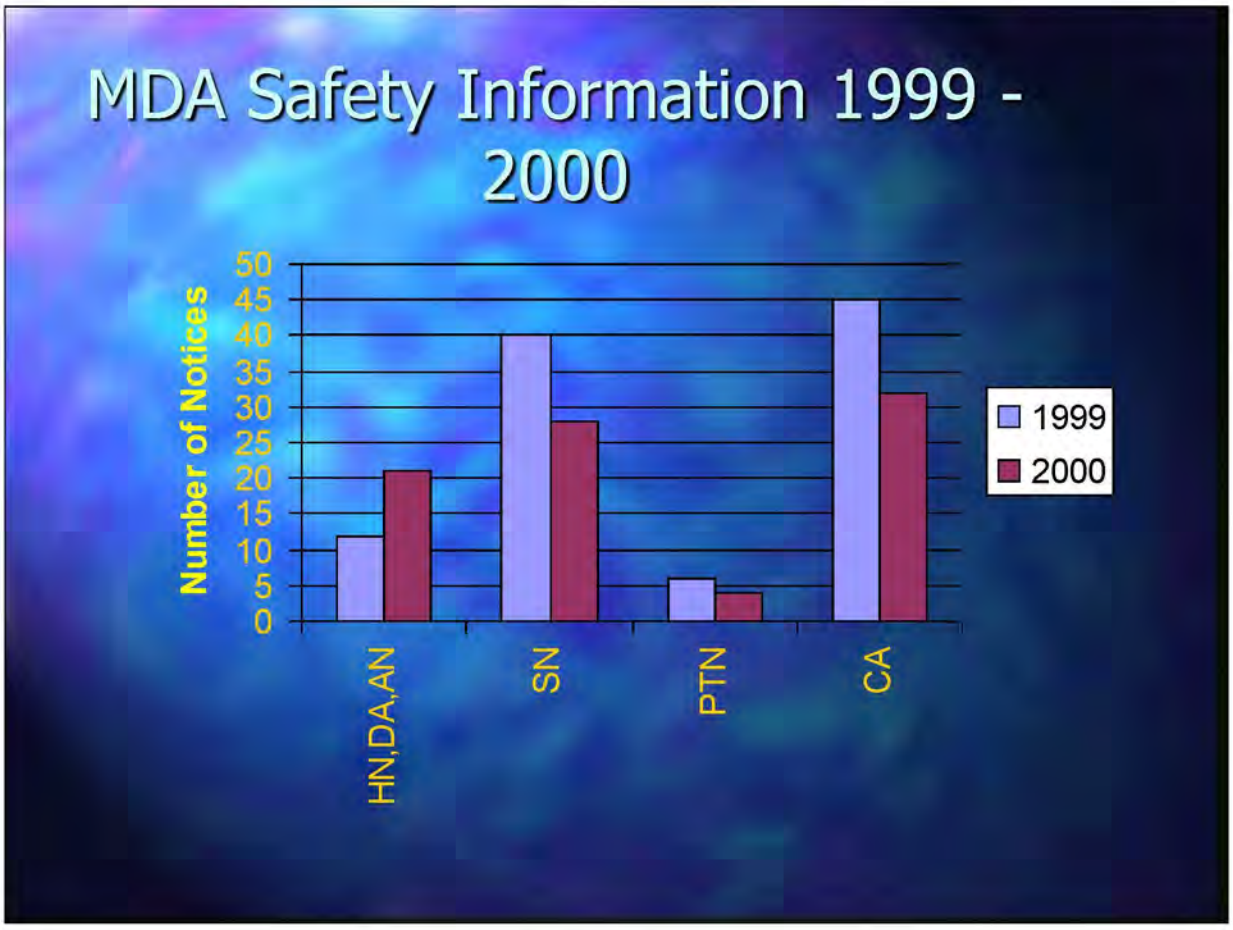
- published 51 Safety Warnings
- supervised or had active involvement in 99 product recalls or field correction and monitored a further 122 cases; and
- provided advice on safer device use or on improving staff training in 173 cases.
- In 1,015 cases manufacturers undertook to improve their design or manufacturing systems

Causes of adverse incidents in 2000





Worth pointing out on this slide that even though for over 45% of reported incidents no further action was considered necessary these incidents are analysed for trends and clusters on a routine basis.



Number of Hazards and SABs appear to bear no relationship to any other data:
- neither to reports received, nor files opened
- ratio of Hazards to SABs varies for no apparent reason
- peak in 1990 partly due to food activity, responsibility now lost
- dip in 1992 probably due to disruption leading up to reorganisation, rather than any change in nature of reports

DTS procedures now document the criteria for choosing Hazard or SAB

Next step is analysis and rationalisation of all risk assessment events from report from the receipt of a report to the closure of a file, eg:
initial handing, obtaining medical, nursing or other advice, file or LPD action, laboratory assessment or not, site visit or not.....

Move onto the conclusion, which is 5 slides summarising future developments and improvements which we have in hand .....

The MDA leverage/ guidance programmes

Examples

- infusion systems programme
  - education
  - study days
- controls assurance DB 9801
- decontamination and sterilisation
- Primary care
  - Equipped to Care
  - Devices in practice

The MDA leverage/ guidance programmes

- Cot sides programme
- Committee on the Safety of Devices initiatives- diathermy
- IVD awareness day

Further information

Device Bulletin: Adverse Incident Reports 2000

(DB 2001(01)

MDA Web Site

http://www.medical-devices.gov.uk