

*The Total Product Life Cycle
Focus on Post Marketing
Surveillance and Vigilance
UK View*

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Issues

- importance of PMS for medical devices
- requirements/review of the Directive
- review of the Directives
- objectives of PMS
- Methodologies
- new approaches
- Longer term safety monitoring

Issues

- Comparison and lessons to be learnt from the pharmaceutical sector
- zero tolerance for safety
- precautionary principle

PMS for Medical Devices

- Importance
- identify user issues
- validation of surrogate endpoints
- dynamics of medical device products
- objectives of PMS
 - identify new problems
 - provide reassurance
 - targeted PMS
 - identify new users

Functions

- Risk identification
- risk analysis
- risk management
- risk communication

Post Marketing surveillance
should be seen as part of risk
management strategy

Limitations of Conformity Assessment

- Power calculations (see slide)
- comparison with pharmaceuticals
- Size of the studies
- power calculations(pool size 3m)
- experience in normal conditions of use

Number of patients required to be 95% certain of detecting 1,2& 3 cases of an adverse incident

Incidence	1 case	2 cases	3 cases
1:100	300	480	650
1:200	600	980	1300
1:1000	3000	4800	6500
1:2000	6000	9600	13000
1:10,000	30000	48000	65000

Methodologies

Authorities

- spontaneous adverse incident reporting
- Vigilance and user reporting schemes
- Registries
 - Breast implants
 - Joint implants
 - heart valves
 - hydrocephalic shunts

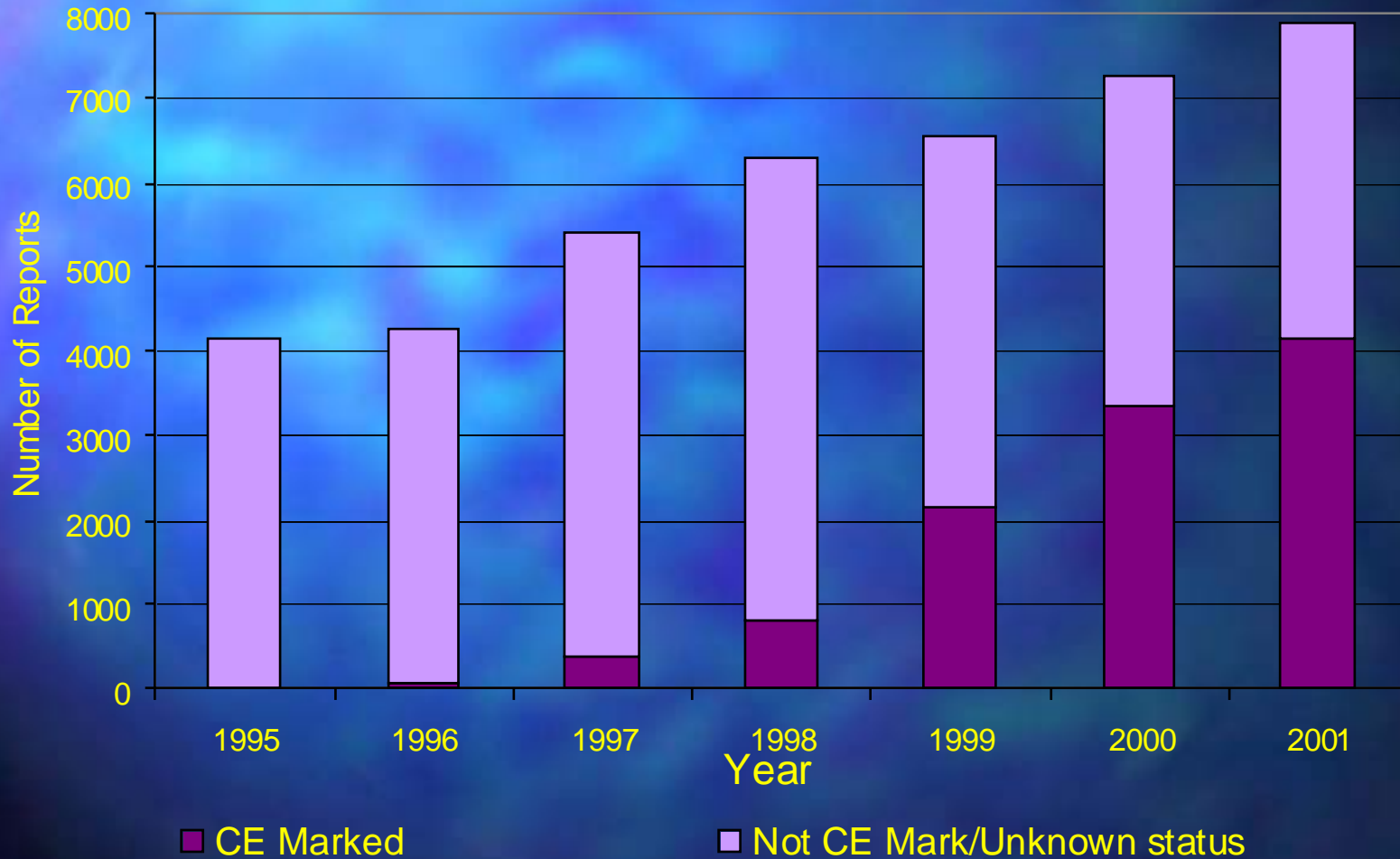
UK National Patient Safety Agency

- New safety agenda
- no blame culture
- learning from errors
- total capture

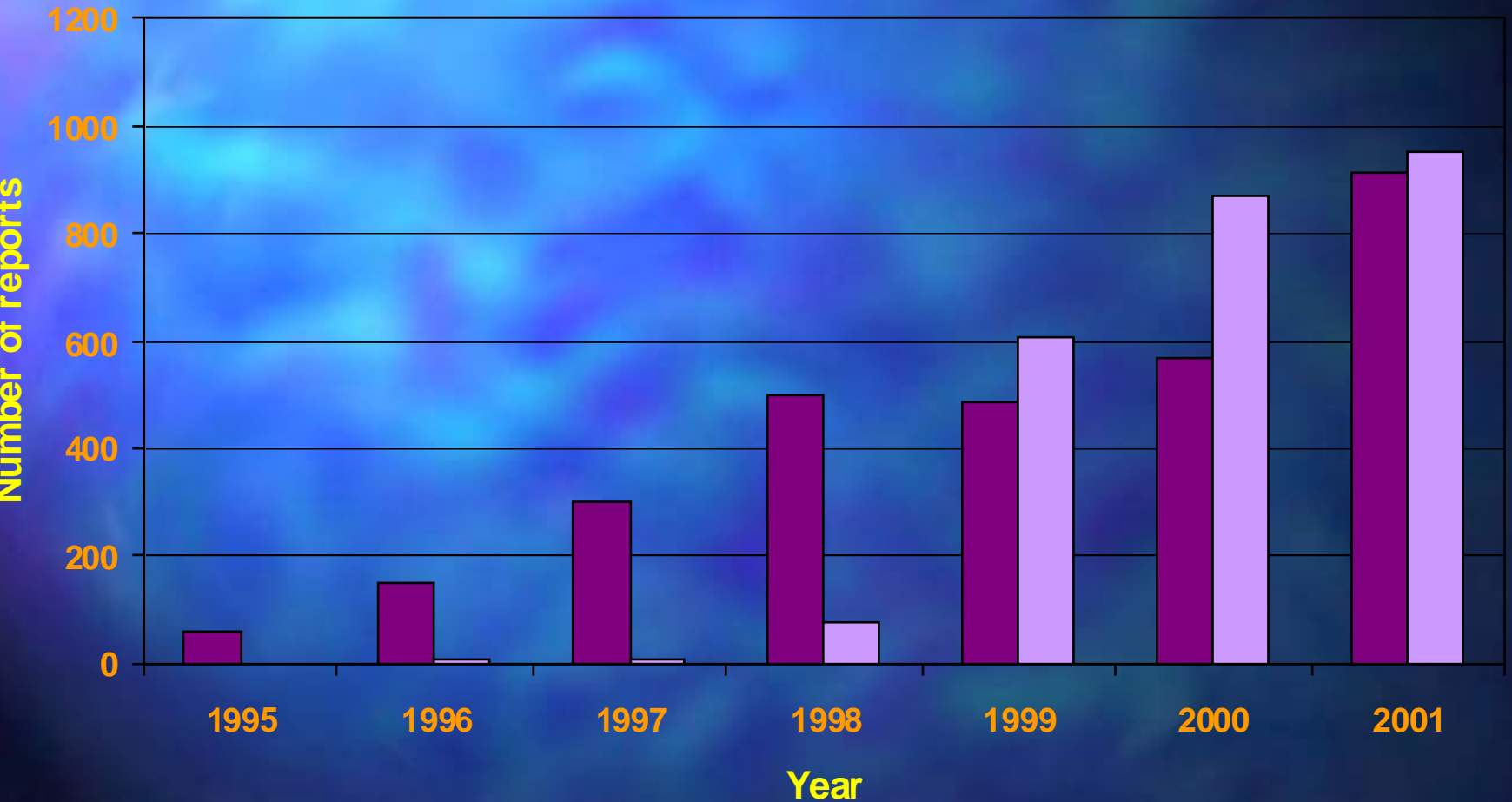
MDA

- Vigilance experience
- user adverse incident reporting scheme

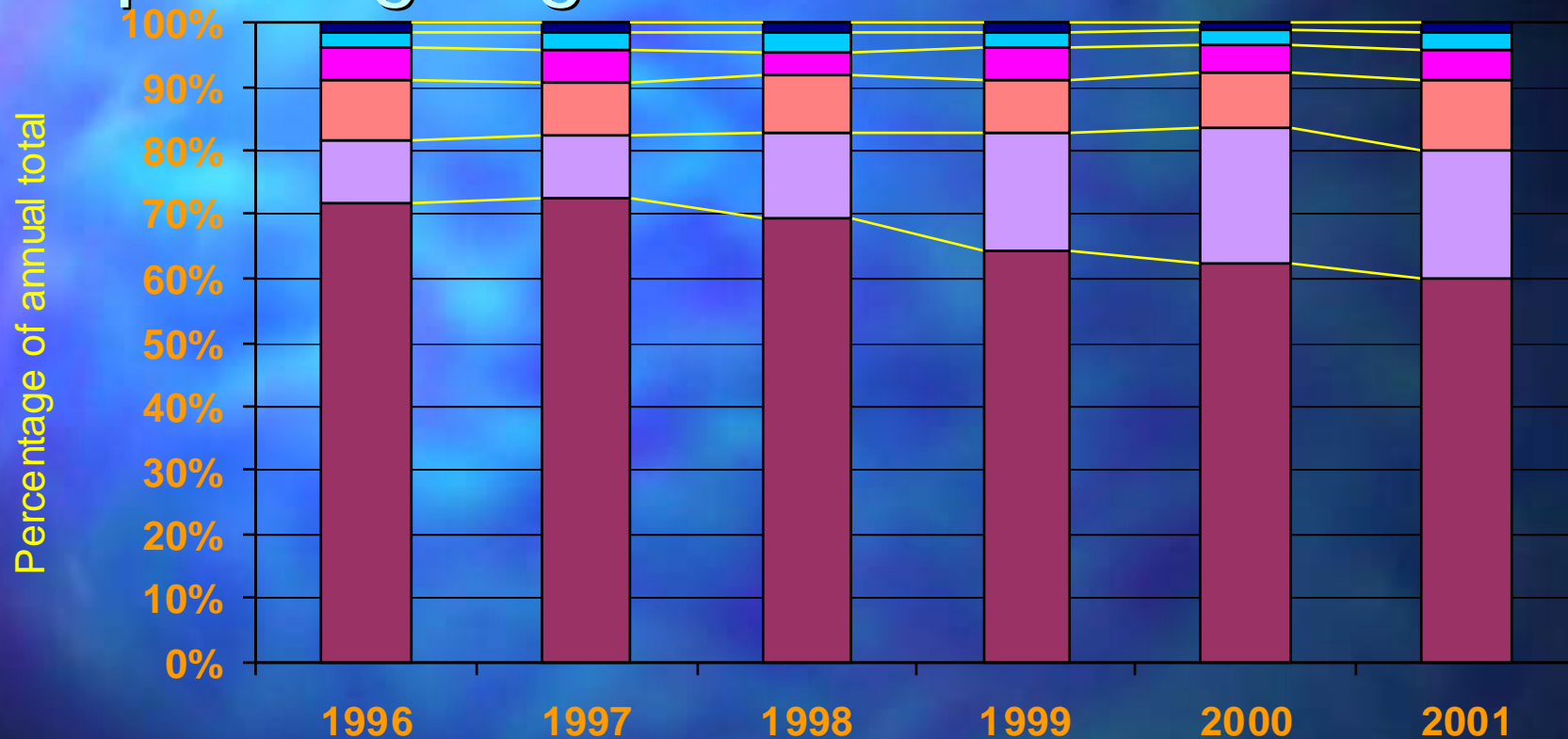
Reports received by MDA: 1995 to 2001



Reports handled as Vigilance 1995 - 2001



Reporting organisations 1995-2001



NHS

Other Government Bodies

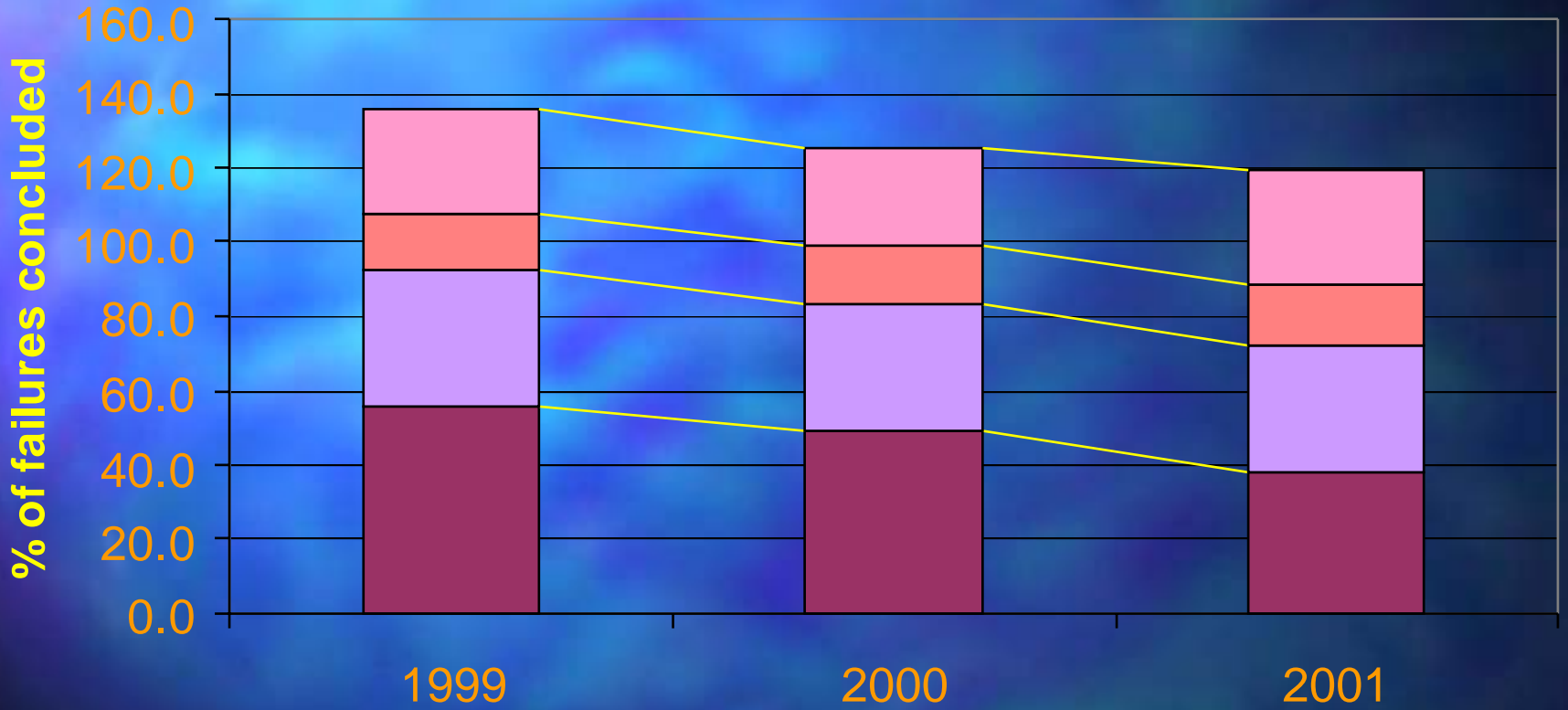
Non-Government Organisations

Manufacturers

Overseas Reporting Organisations

Private Healthcare Organisations

Causes of adverse incidents in 1999-2001



■ Device faults - before delivery

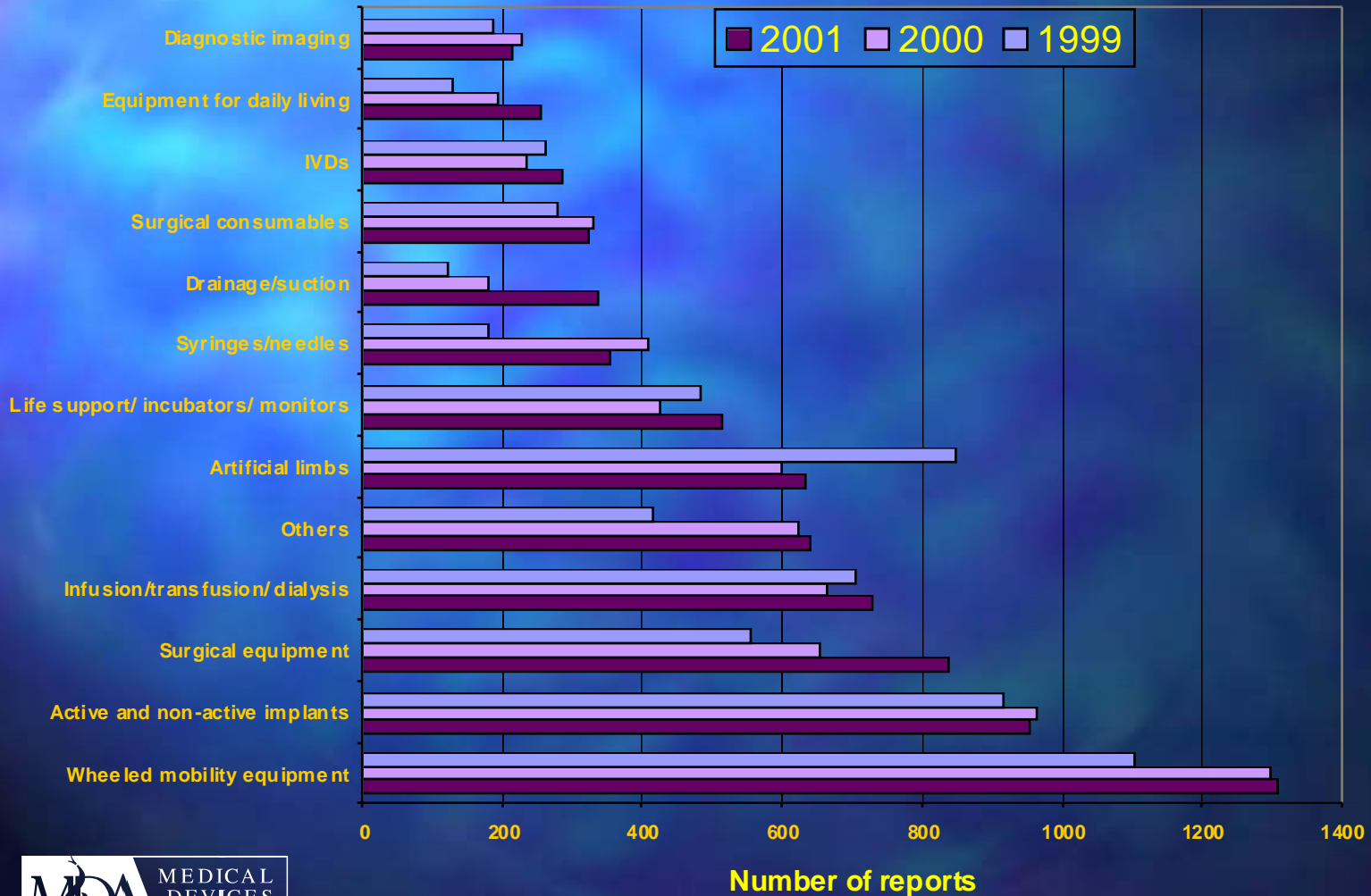
■ Device faults - after delivery

■ User error

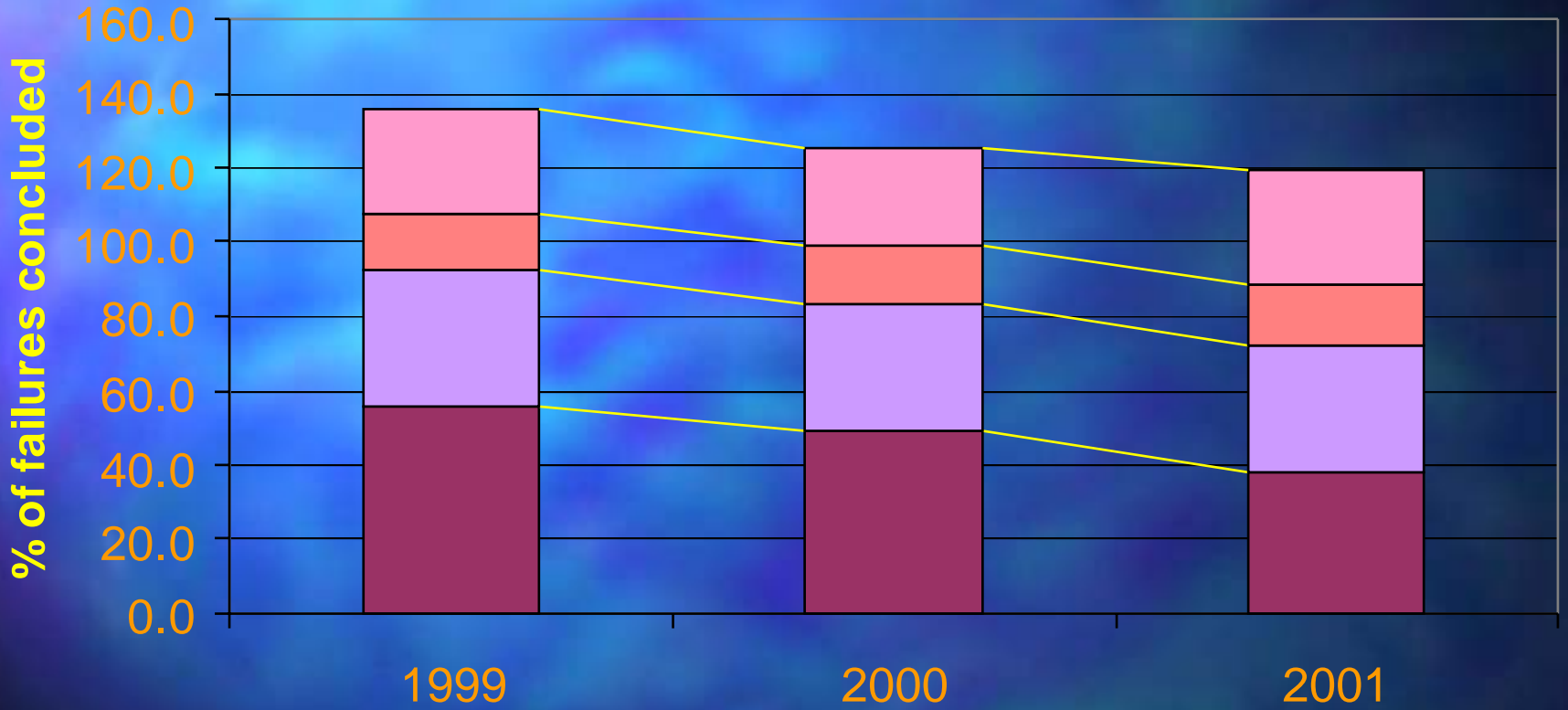
■ No established link to device



Top 12 device categories in 1999-2001



Causes of adverse incidents in 1999-2001



■ Device faults - before delivery

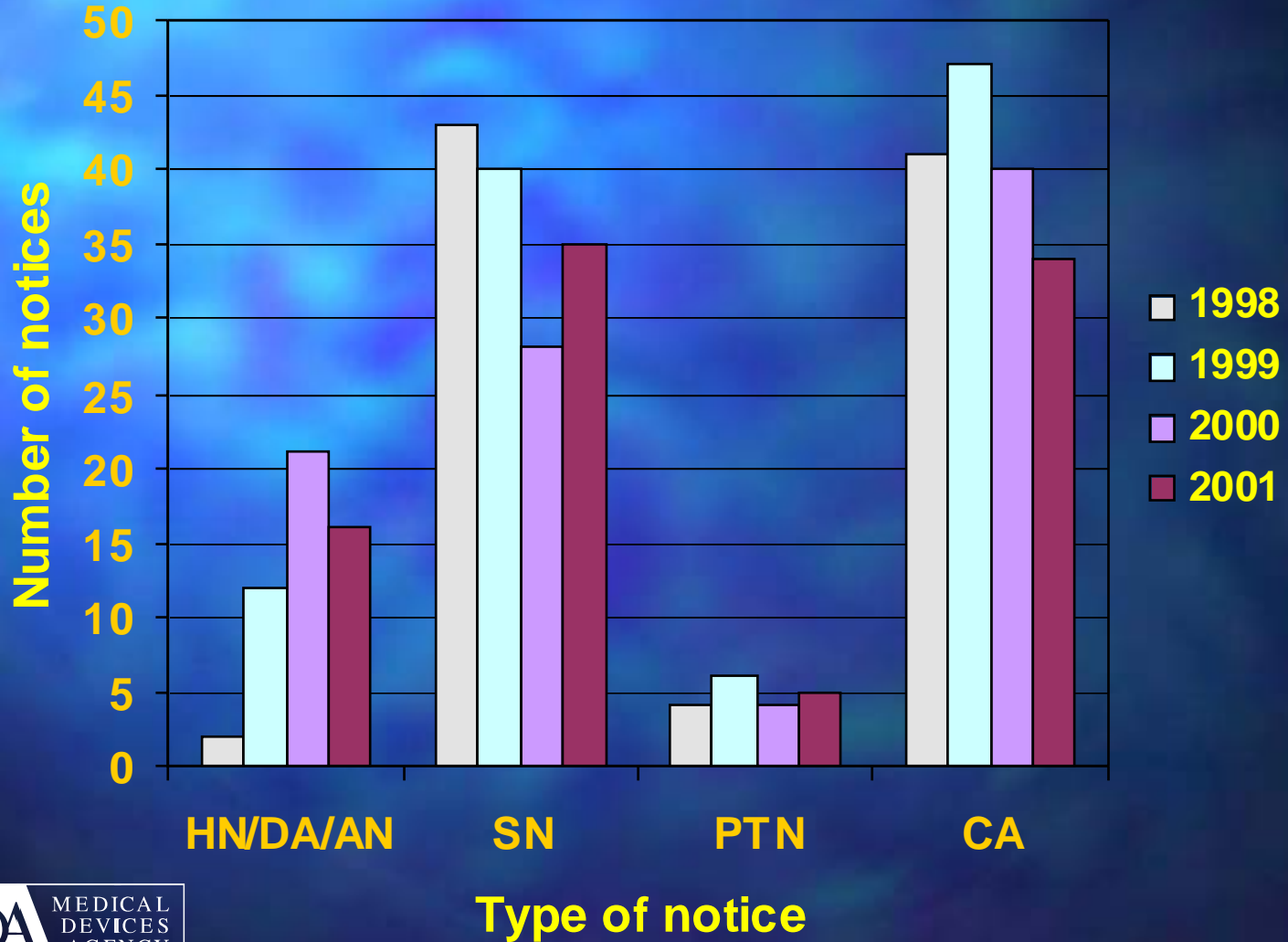
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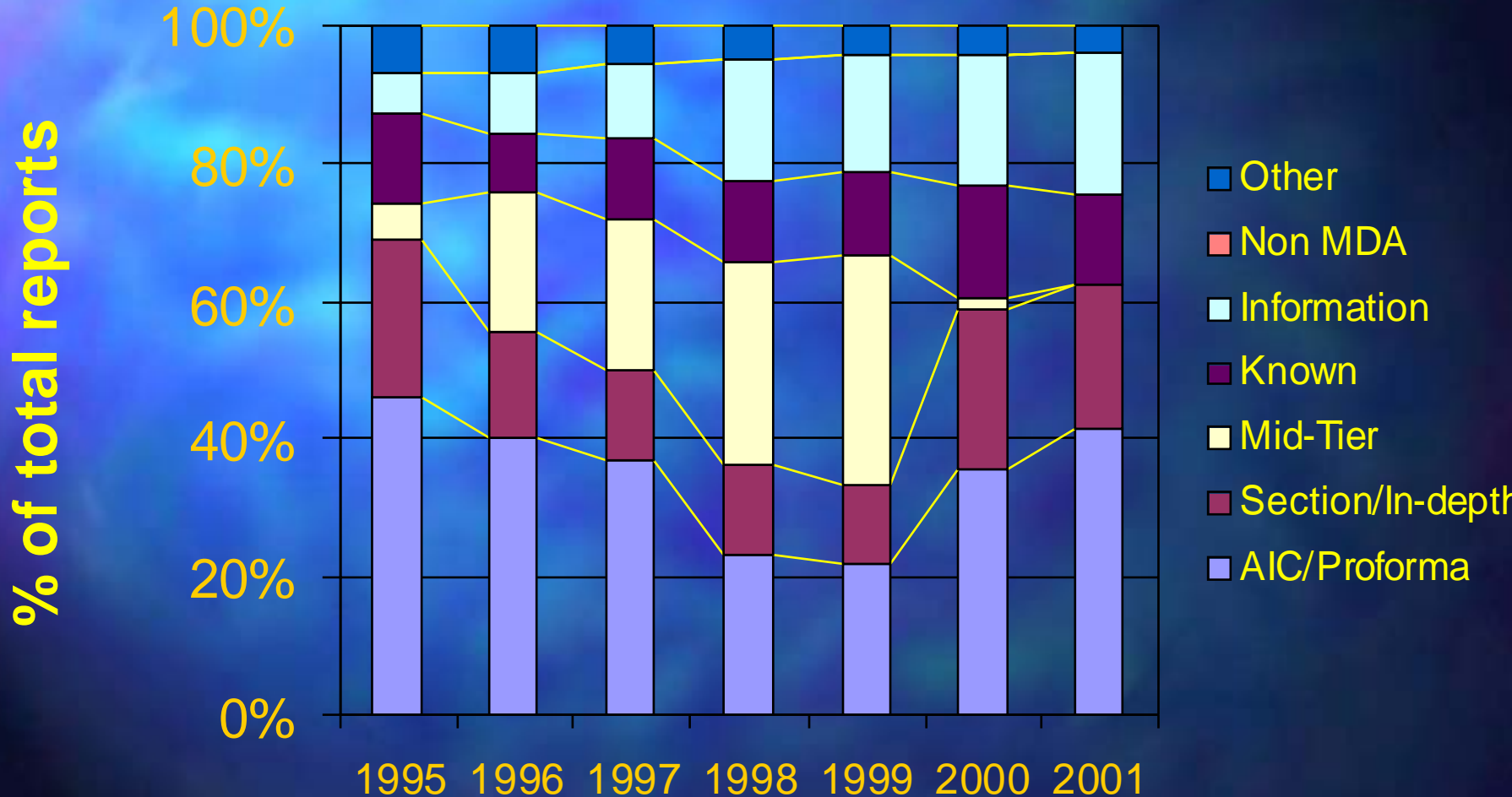
■ No established link to device



MDA Safety Information 1998 - 2001



Action on Reports 1995-2001



Other Methodologies

- Targeted PMS (phase 4 studies)
examples

- case control studies

- record linkage studies:

GPRD - longitudinal database

MEMO

PEM- prescription event
monitoring

Recent PMS issues

- Silzone Heart valve
- Hylamer hip
- Baxter Dialyzer
- Single use tonsillectomy
- Trilucent breast implants
- Anaesthetic tubing
- Intra-ocular lenses

Limitations of Spontaneous Reporting Schemes

Comparisons with pharmaceuticals

- Common issues - long term safety
- larger pre-marketing database
- product stability for pharmaceuticals
- medical devices - importance of:
 - life cycle
 - user issues
- intensive monitoring (black triangle scheme)
- targeted PMS
- validation of surrogates

Lessons from pharmaceuticals

- Periodic safety update reporting
- Eudawatch systems
- international co-operation

Current Issues

- Improve standards of data collection and exchange
- further enhanced international co-operation and exchange
- explore new approaches

New approaches

- Monitoring I.V.D.s
- Tissue engineering products
- long term safety issues