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When did the situation become serious - with patient safety and major cost issues apparent?

When did the clinicians begin to <u>not</u> know which laboratory tests to select?

When did the clinicians begin to <u>not</u> fully understand the clinical significance of test results - except for the commonly ordered assays?

Scientific Developments : Coagulation Example

2 Anticoagulants
No relevant
lab tests

Major advances
in imaging to
detect clot

D-dimer ELISA
able to rule out clot

1970 1980 1990 2000 2010

Radiographic/
vascular studies
to detect clot

Hypercoag test
panels into lab

>10 Anticoagulants
>20 relevant
lab tests

Clinical Laboratory Testing

30-50
lab tests

RIAs
for hormones

Intro of
molecular testing

>5000
lab tests

1970 1980 1990 2000 2010

Intro of
automated
instruments

Immunoassay
automation

Major expansion
of molecular
testing

36 Years of Personal Observation		Regarding Lab Tests
1972	Witnessed clinical lab testing in 200 bed community hospital for 1 month	All Docs know most of what they need to know
1982 -1985	Residency in laboratory medicine at Washington University	Confusion emerges: Prolonged PTT Evaluation? Which factors?
1985 – 1989	Coagulation Lab Director at the University of Pennsylvania	A clear problem exists but specialty consult services reluctant to accept consultative provided by lab directors to anyone
1989 – 2008	Director of Clinical Laboratories Massachusetts General Hospital	The problem worsens rapidly with major growth of test menu and cost of lab tests–specialists interest in lab consultation becomes little to none
2008 -	Pathologist-in-Chief at Vanderbilt University Hospital	

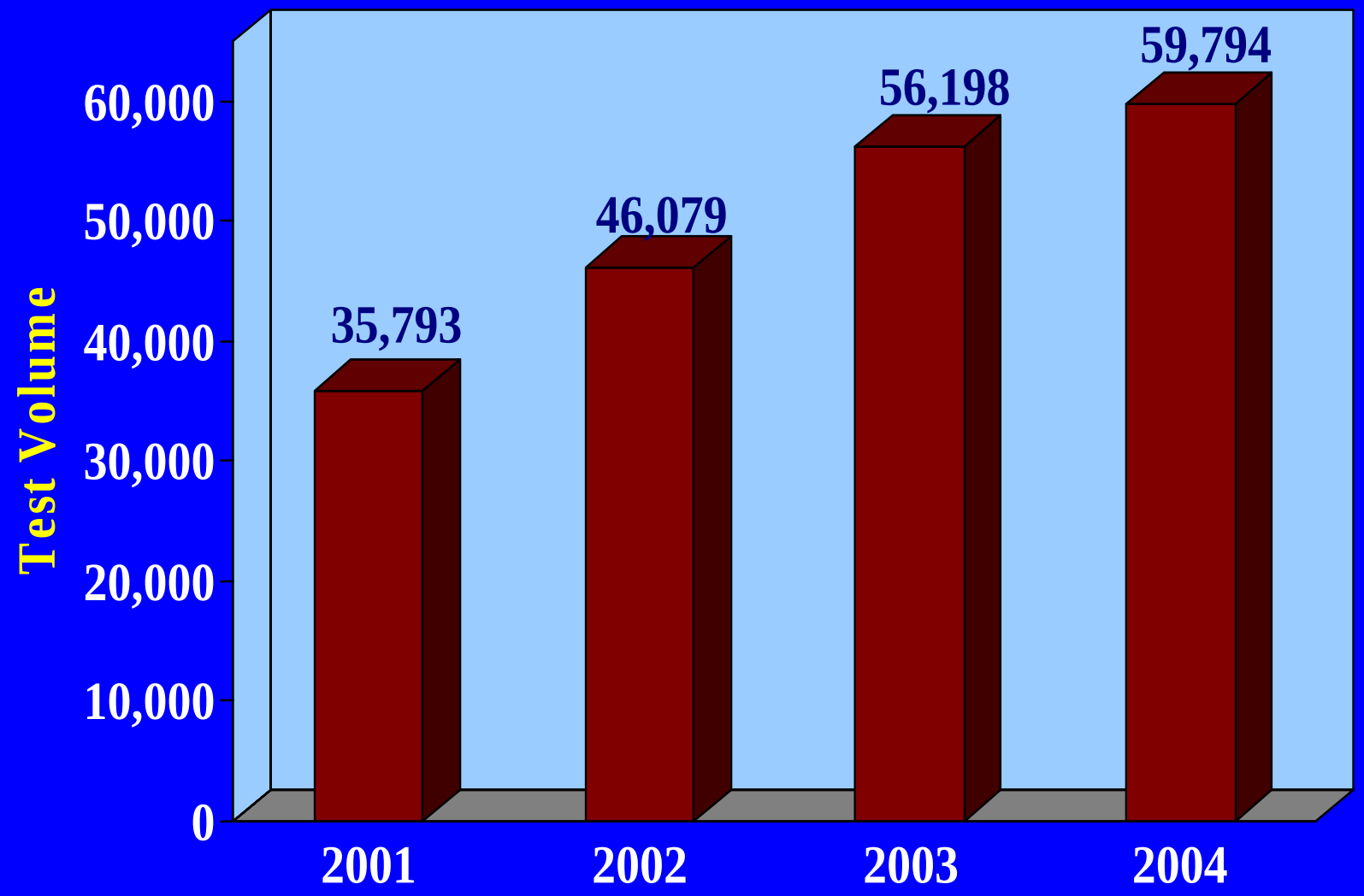
As of 2008:

- The literature clearly describes the problem- Most clinicians readily admit that there are too many clinical lab tests to know which ones to select and to fully understand the clinical significance of many tests
- Too few true experts exist in lab medicine able to perform clinically valuable interpretations
- Prototypes of solutions to improve test selection & result interpretations exist
- Impact on patient safety from lab test related mistakes beginning to emerge as safety considerations move beyond surgical and pharmaceutical issues

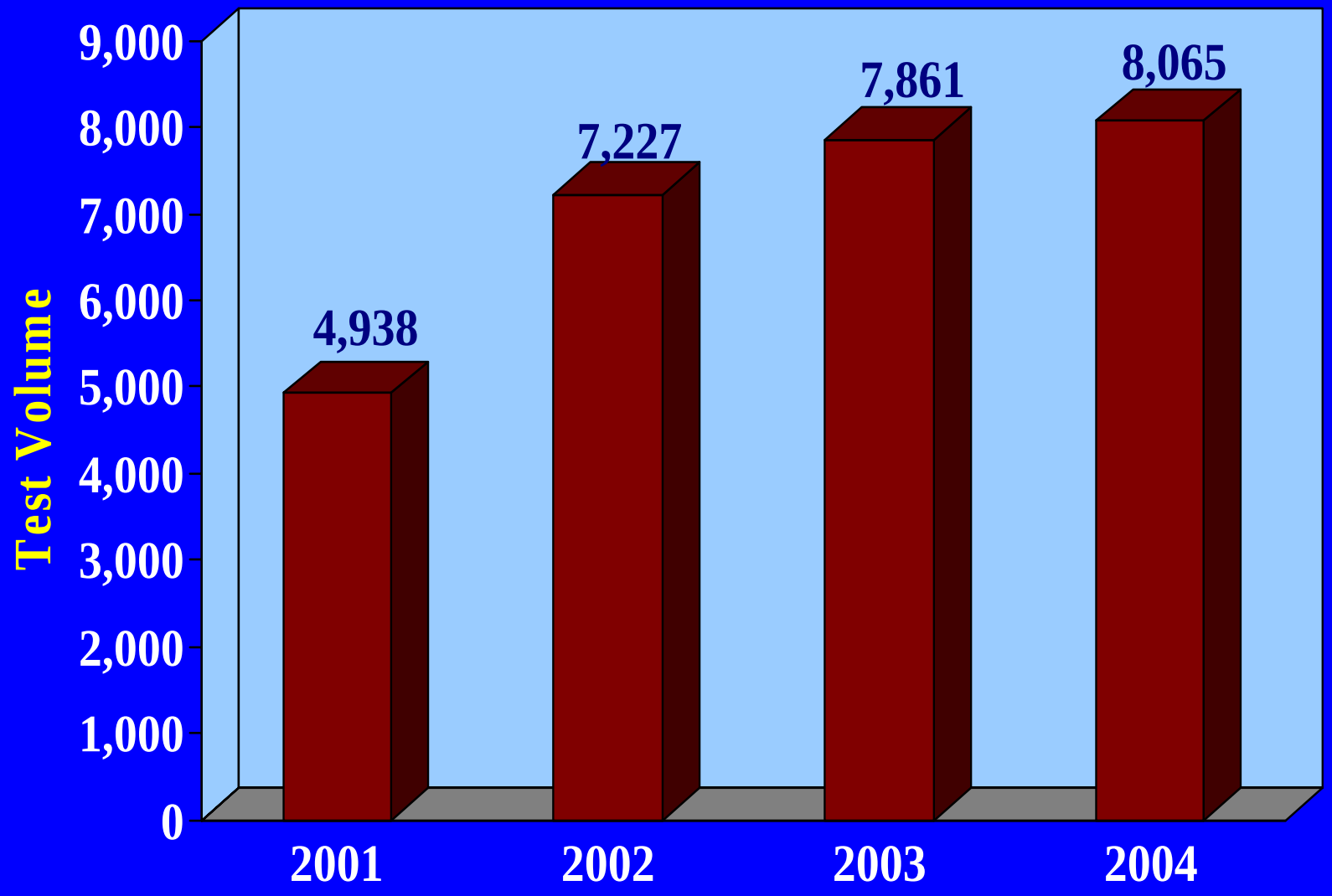
Evolution of the Prototype

1993	Informal discussion of test results with clinicians caring for patient
1995	Billing for interpretations initiated; and case interpretations prepared using no enabling software other than simple word processing
1998	Emergence of enabling software to make sign-out of cases efficient & permit growth of service

Total number of special coagulation tests at the Massachusetts General Hospital



Patient-specific coagulation interpretations performed at the Massachusetts General Hospital



Evolution of the Prototype

2004	Recognition by institute for quality in laboratory medicine/CDC of importance of prototype to medical practice
2007	Expert groups organized & convened by CDC to address the need for improved test selection & result interpretation
2008	The clinical laboratory “integration” group is formed by the CDC

Goals of the Clinical Laboratory Integration Group Formed in 2008

Identify the challenges & the barriers to success for optimized laboratory test selection

Identify the challenges & the barriers to success for correct result interpretation by clinicians

Produce Manuscripts
Promote Policy Development
Produce Guidelines

Organize a system whereby any healthcare provider in any location has an extremely high likelihood to select the right tests & know how to interpret the results

Dr. John Hickner,
Co-Leader of the Integration Group,
will describe the
activities of our group
after 9/21/08 –

The date of our face-to-face group meeting in Chicago

The Clinical Laboratory Integration Work Group

A Work Group of the Center for Disease Control and Prevention
Division of Laboratory Systems

Charge to the Integration Work Group

- Identify and champion models of patient care that integrate clinical consultation provided by laboratory professionals into the selection of laboratory services and the interpretation of test results.

- Promote the development of training/education courses and programs that link clinicians, clinical and public health laboratory providers and patients.

First We Identified 8 Problems

- Too many lab tests from which to select.
- Inconsistent test nomenclature across laboratories.
- Inconsistent guidelines for laboratory test use.
- Lack of education on clinical consultation during training of laboratory directors.

First We Identified 8 Problems

- Limited or ineffective communications between the laboratory and the clinicians within an individual institution.
- Engaging the laboratorian in consultative medicine.
- The limited knowledge of clinicians about how the laboratory functions and how to interpret test results.
- Difficulty in effectively introducing new laboratory tests to physicians and to the public.

Next, we discussed approaches to these problems

- Scholarly work
- Participation in national guideline organizations
- Development and dissemination of tools for clinicians to improve test ordering and interpretation
- Identification and recruitment of others interested in these projects
- Advocacy

Then we identified target audiences

- Practicing clinicians, residents, medical students,
- laboratory directors and lab section directors (MD and PhD)
- Organizations
  - AMA, American Board of Medical Specialties, AMA, American Association of Medical Colleges, Accreditation Council on Graduate Medical Education
  - Laboratory medicine organizations

Initial Project List: Research

- Systematic literature review
- Survey Research
  - Survey of medical schools regarding lab curriculum
  - Survey of clinicians: what do they perceive are the problems?
  - Survey to assess need for and barriers to consultative services from laboratorians
- Identify and disseminate effective models of laboratorian consultative services

Initial Project List: Other

- Develop a list of recommended abbreviations for test ordering forms
- Identity collaborators in academia, industry, the government and professional societies
- Develop a test-ordering and interpretation manual
- Develop a test-ordering and interpretation newsletter
- (Purposefully avoiding genetic testing)

An Ambitious Agenda Inspired by Joe Boone

We’ve only just begun. . .

Questions?

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