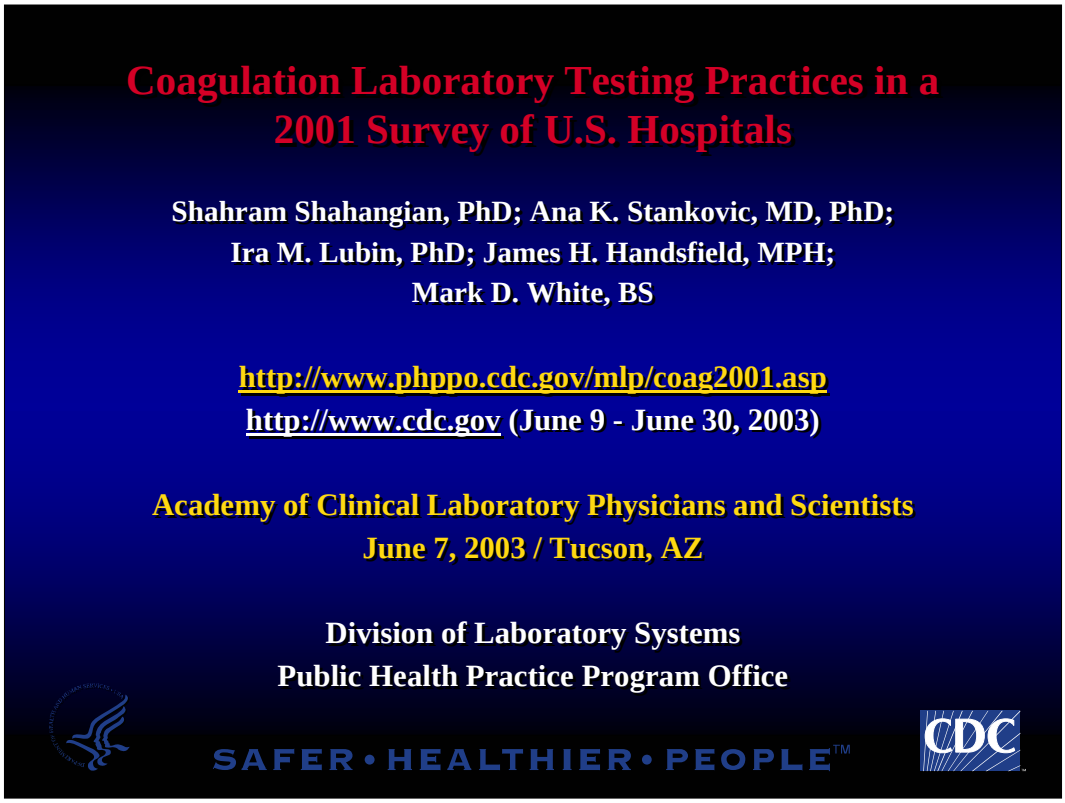
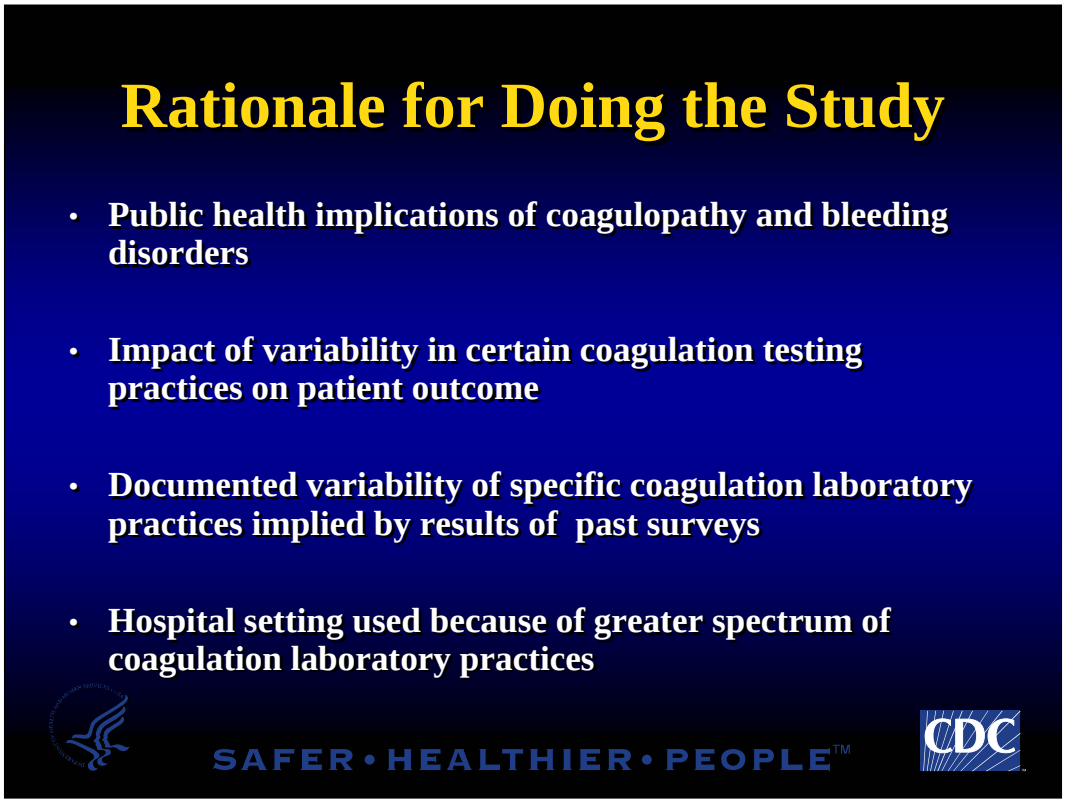


During the next 30 minutes or so, I'd like to present and discuss with you some of the findings from a CDC survey that we conducted in 2001 to assess coagulation laboratory practices in US hospitals.

You can also download the full text of the report in either PDF or HTML format at this URL.



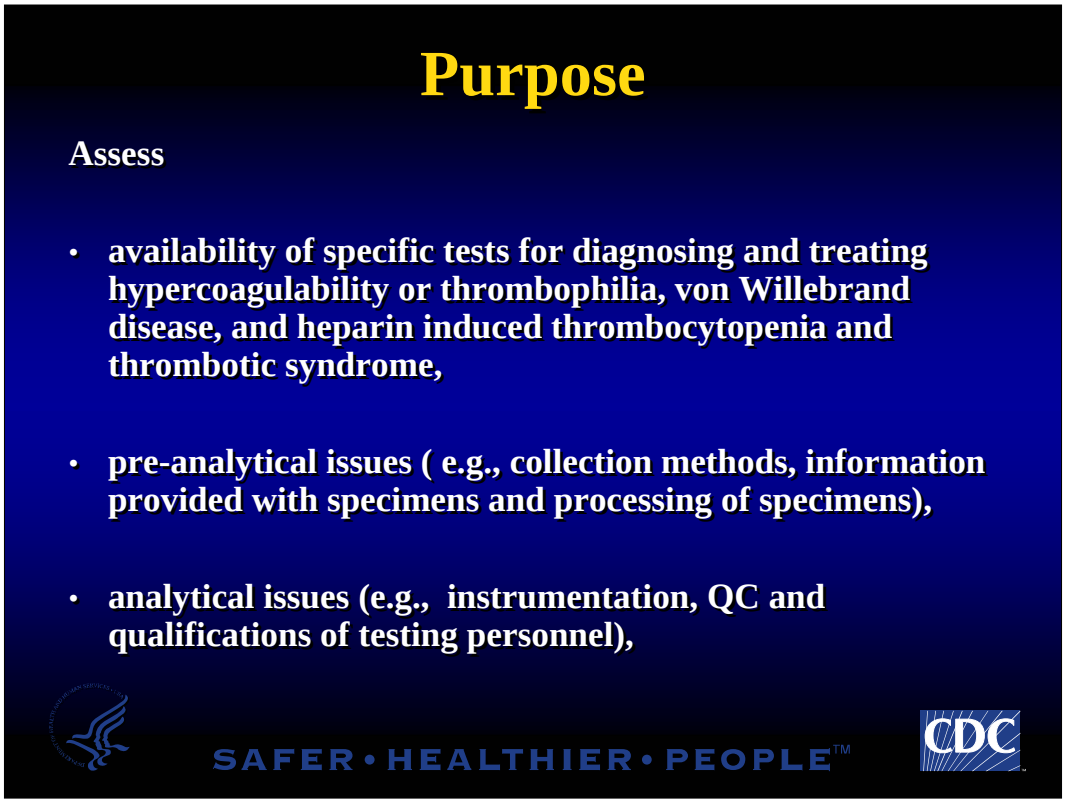
We set out to carry out this study because

•coagulation and bleeding problems have great societal burden of suffering due to their substantial, associated morbidity and mortality;

•variation in testing practices may impact result accuracy and interpretation, and clinical outcome such as bleeding or thrombosis; and

•previous studies have demonstrated great variabilities in certain consequential practices.

We used hospitals as the testing environment to address a broader spectrum of practices that are not amenable to observation in usual office laboratories.



The purpose of this study was to

•evaluate availability of tests for workup of hypercoagulability, von Willebrand disease and heparin induced thrombocytopenia/thrombotic syndrome;

•assess various pre-analytical and analytical stages of the testing process; …

Purpose (Continued)

Assess

- **post-analytical issues (e.g., result reporting, interpretations and recommendations), and**
- **use of selected laboratory practices specific to each test that are subject to variation and critical to diagnostic or therapeutic use of the test.**

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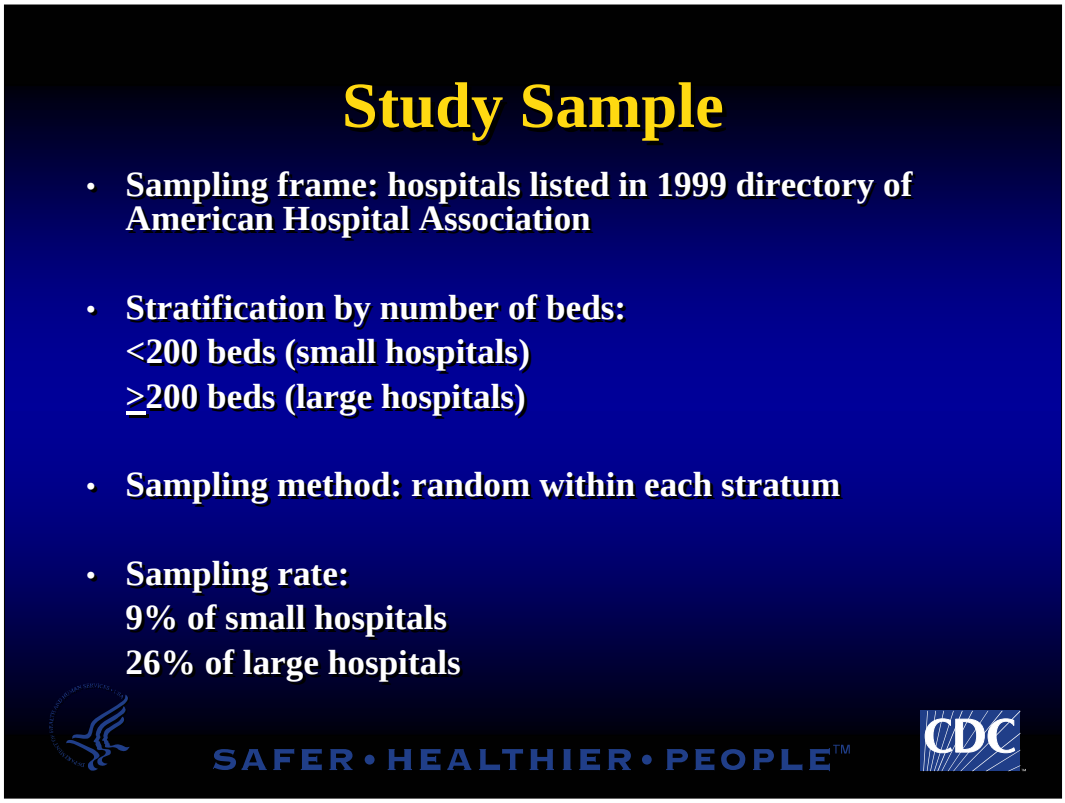
•… evaluate various post-test issues; and

•assess some testing practices critical to patients' management.



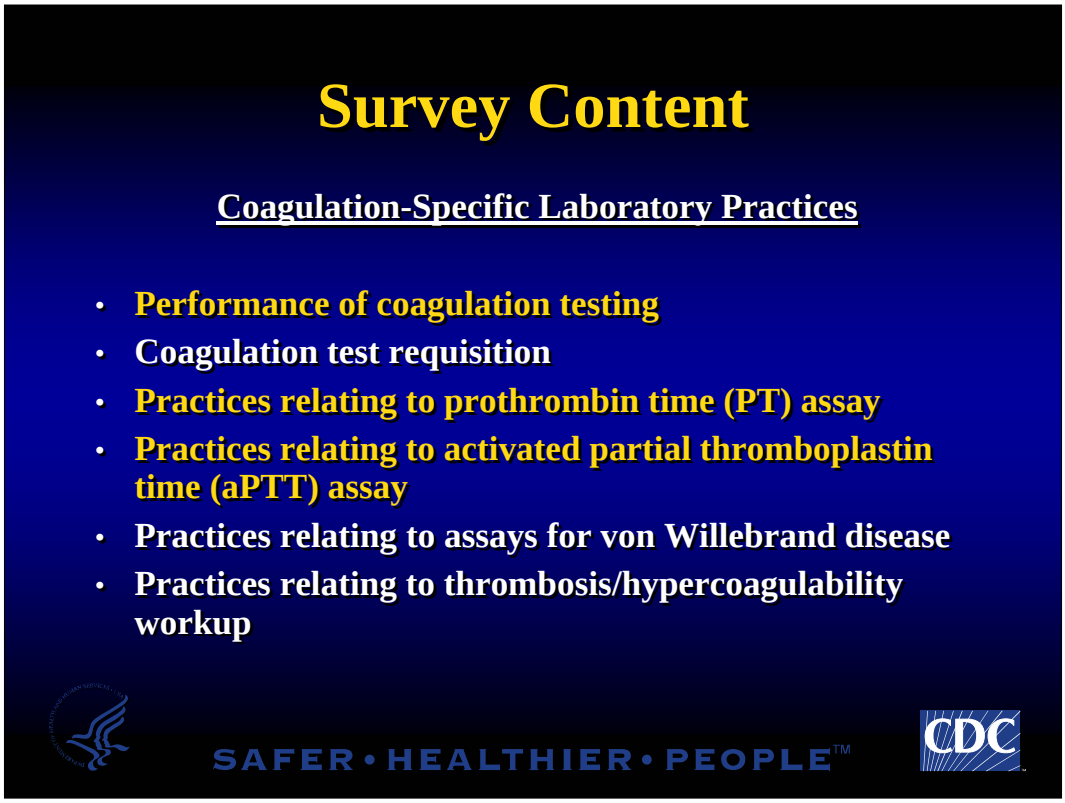
We used hospitals listed in the 1999 directory of the American Hospital Association as the sampling frame…

… and stratified them into 2; those with less than 200 beds, labeled as “small” hospitals and those with equal to or more than 200 beds, labeled as “large” hospitals.

We randomly selected hospitals from these 2 strata—sampling 9% of the small and 26% of the large hospitals.

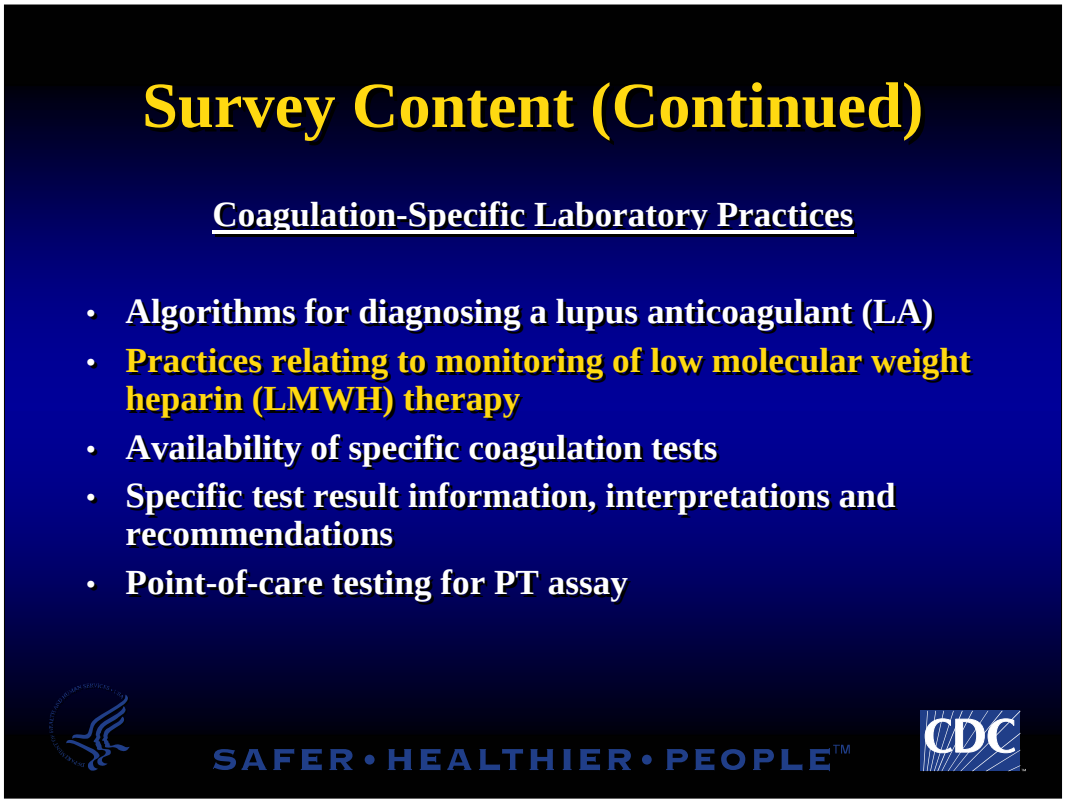
We contacted the 800 hospitals in the sample by mail followed by a reminder postcard 2 weeks later. To solicit response, we subsequently called all but 7 of the institutions not responding.

79% responded. Of those responding, 3% did so via the Internet and the rest mailed the completed paper questionnaire.



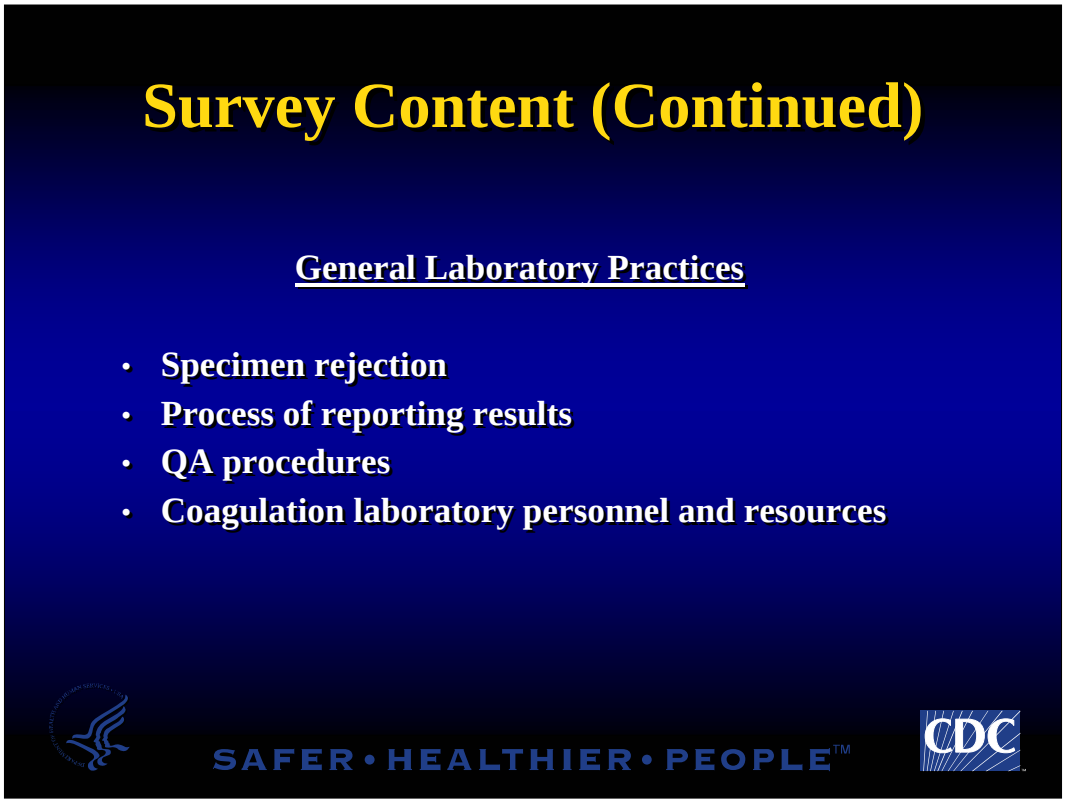
This slide shows some of the coagulation-specific laboratory issues this survey covered from the common PT and aPTT tests to less common testing practices to assess bleeding or thrombotic risk.

Highlighted in gold are the areas which I will partially present during this talk.

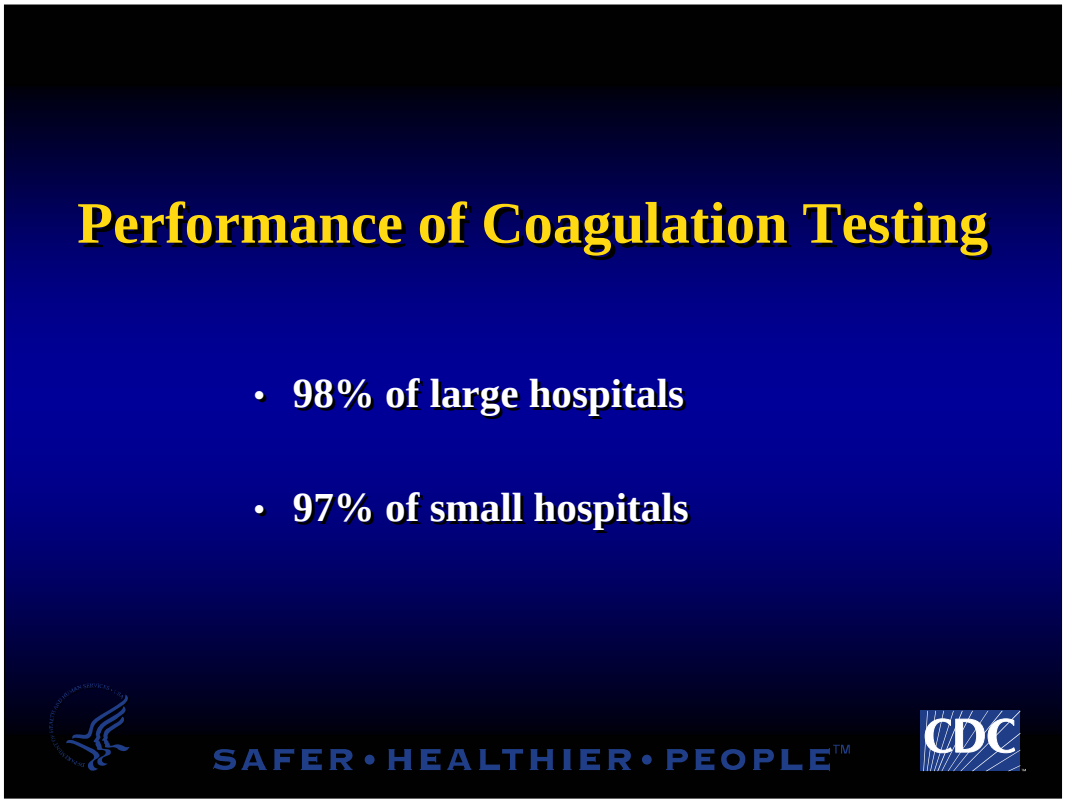


This slide shows other coagulation-specific laboratory issues the survey addressed, ranging from practices to diagnose a lupus anticoagulant and to monitor low molecular heparin therapy to point-of-care testing for PT assay.

Again, highlighted in gold is the area I will partially cover during this presentation.



We also captured data on certain general laboratory practices, relating to specimen management, reporting of results, quality assurance, and human and facility resources which I will not present.



97% of the respondents reported performing coagulation testing. All subsequently analyzed data I will present relate to these respondents.

Practices Relating to PT Assay

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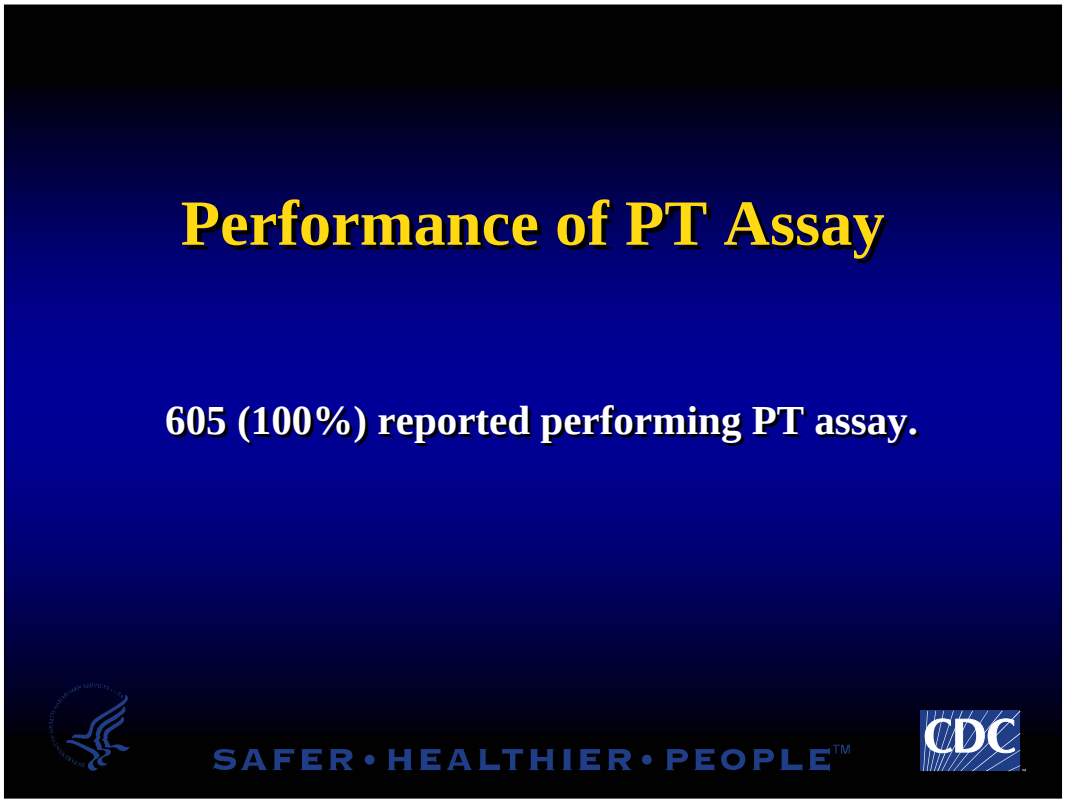
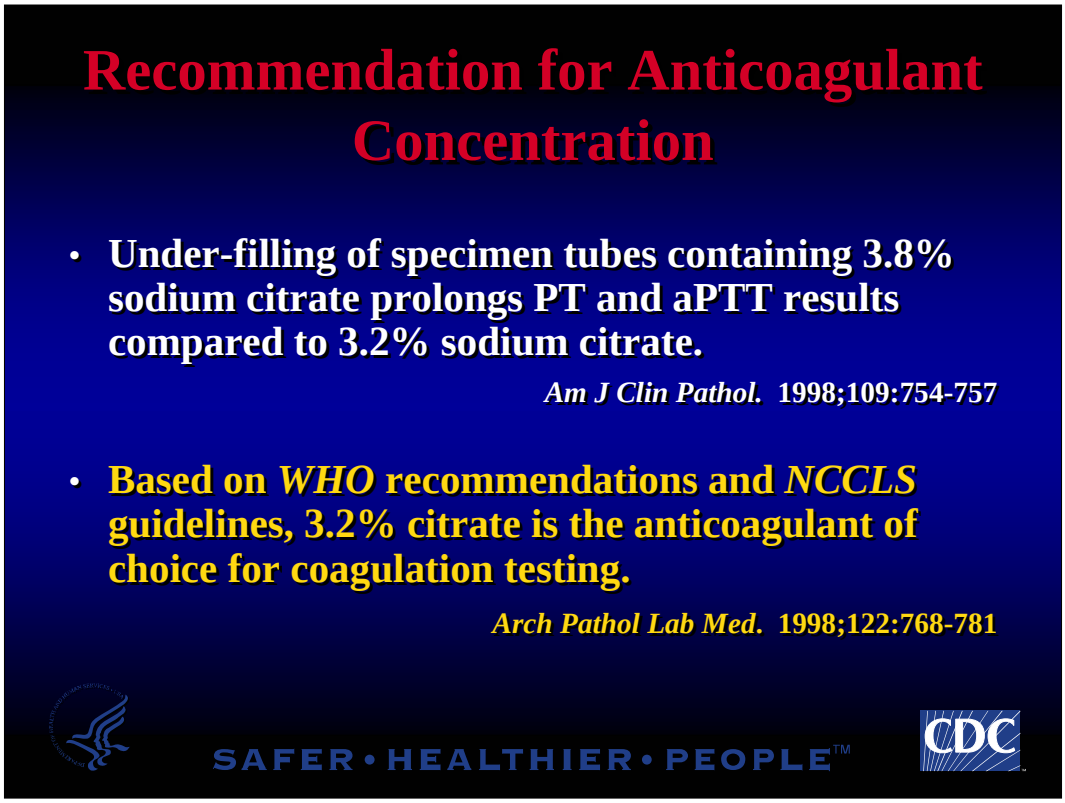


All reported performing PT assay.



Under-filling of 3.8% citrated tubes has been reported to prolong PT and especially aPTT results.

Both NCCLS and the World Health Organization recommend using 3.2% citrate as the anticoagulant of choice.

Anticoagulant Concentration Used

Concentration	No. (%*) of large hospitals	No. (%*) of small hospitals
3.2% (109 mmol/L)	244 (81%)	193 (68%)
3.8% (129 mmol/L)	60 (20%)	96 (34%)

*Percentages total >100% due to 8 respondents (4 large and 4 small hospitals) noting that they used both concentrations of sodium citrate.

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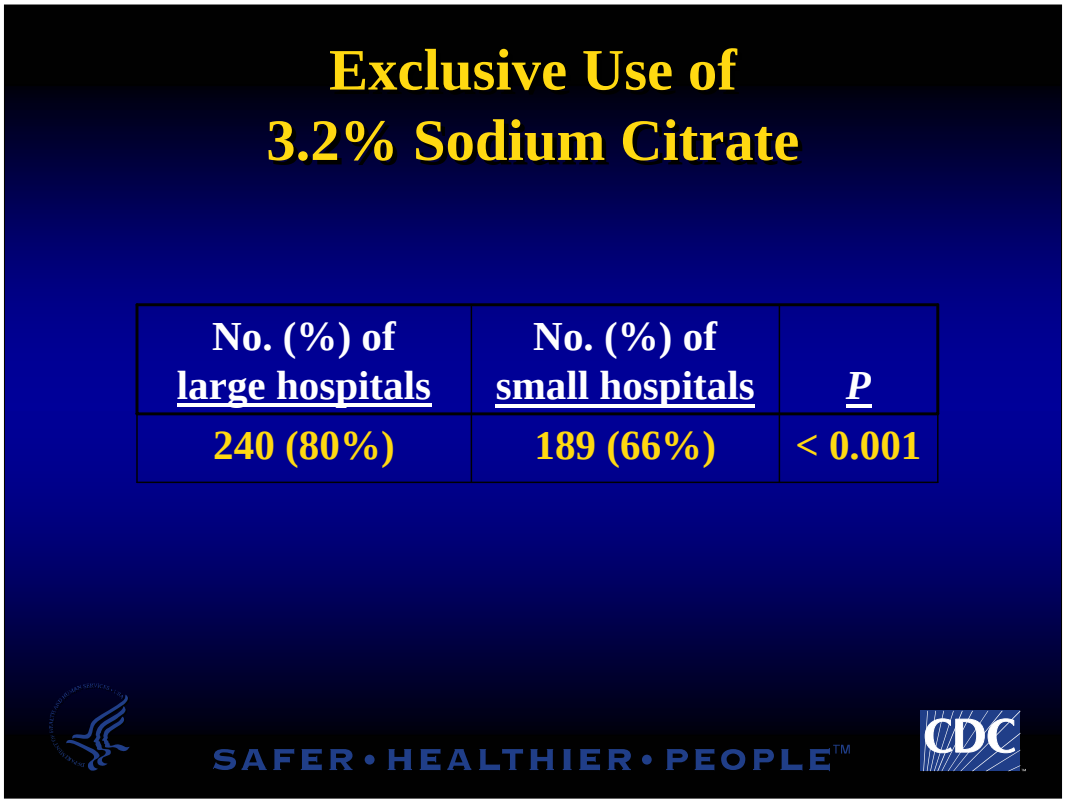
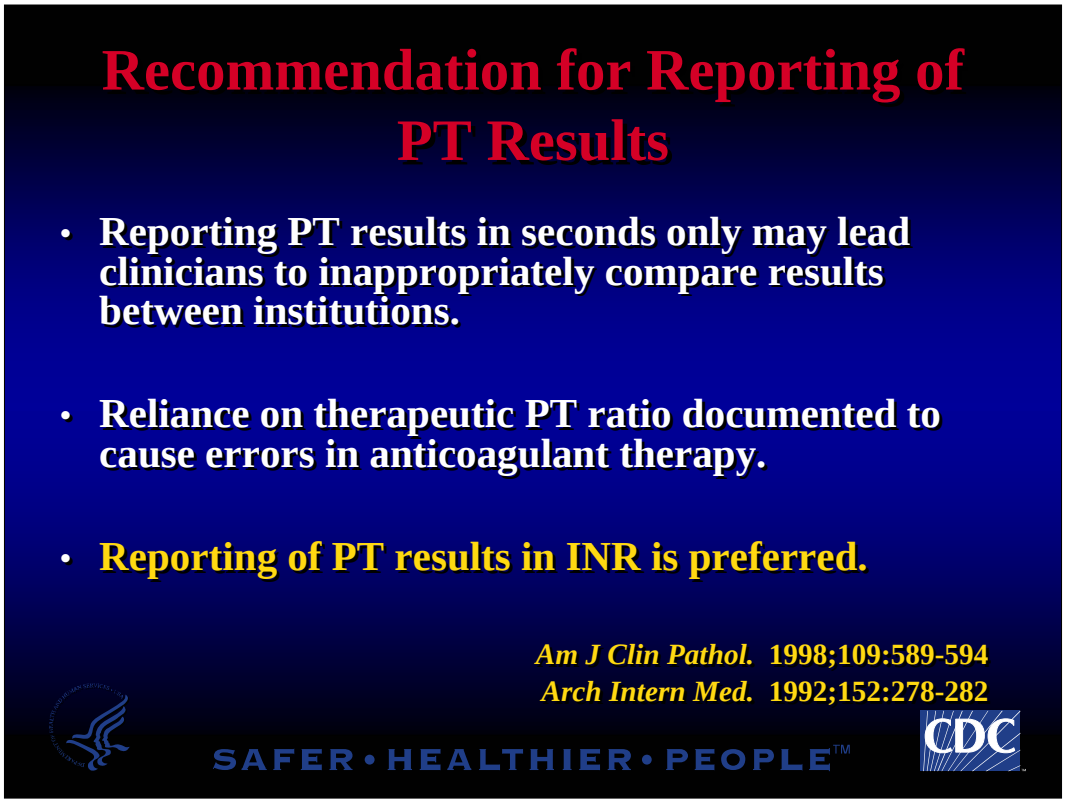
Although most respondents to this survey reported using 3.2% citrate, 20% of large hospitals and 34% of small hospitals reported using 3.8% citrate as the anticoagulant.



In agreement with NCCLS and WHO recommendations, a significantly greater proportion of large hospitals exclusively used 3.2% citrate compared to small hospitals.



Reporting PT results in seconds only or as therapeutic ratio is not recommended.

Current recommendation calls for PT results to be reported in international normalized ratio or INR.

Reporting of PT Results

Results reported in	No. (Proportion)
International normalized ratio (INR)	601 (100%)
Seconds	577 (97%)
Therapeutic PT ratio	77 (16%)

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In agreement with the accepted practice, all respondents noted that they reported PT results in INR; 97% also reported PT results in seconds and 16% reported results as therapeutic PT ratio.

Reporting of PT Results (Continued)

Format Used to Report PT Result by U.S. Hospitals and Canadian Medical Laboratories*

Reporting format	U.S., 2001 (n = 626)	Canada, 1996 (n = 649)	Canada, 1992 (n = 857)
Seconds and INR	80%	60%	36%
Seconds, INR and PT ratio	12%	–	–
Not specified	4%	–	–
INR only	3%	36%	15%
INR and PT ratio	0.5%	1.5%	6%
Seconds only	0%	<1%	36%
PT ratio only	0%	1%	7%

**Am J Clin Pathol.* 1998;109:589-594
**Am J Hematol.* 1995;48:237-239

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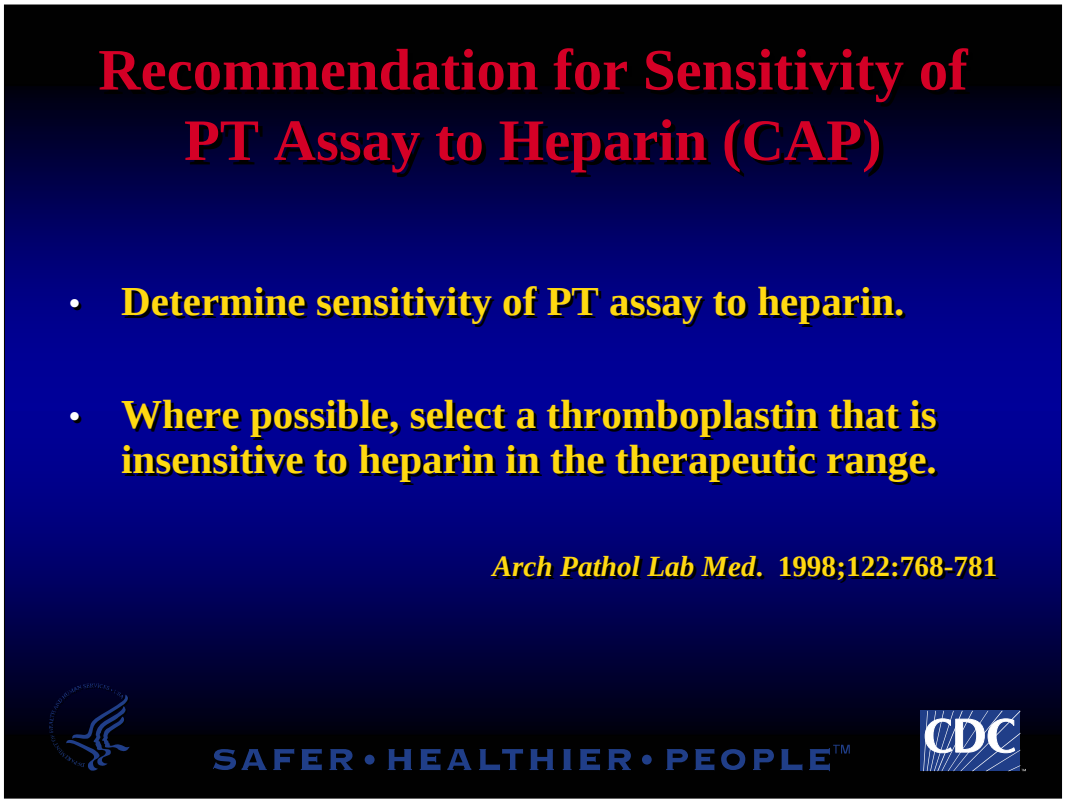
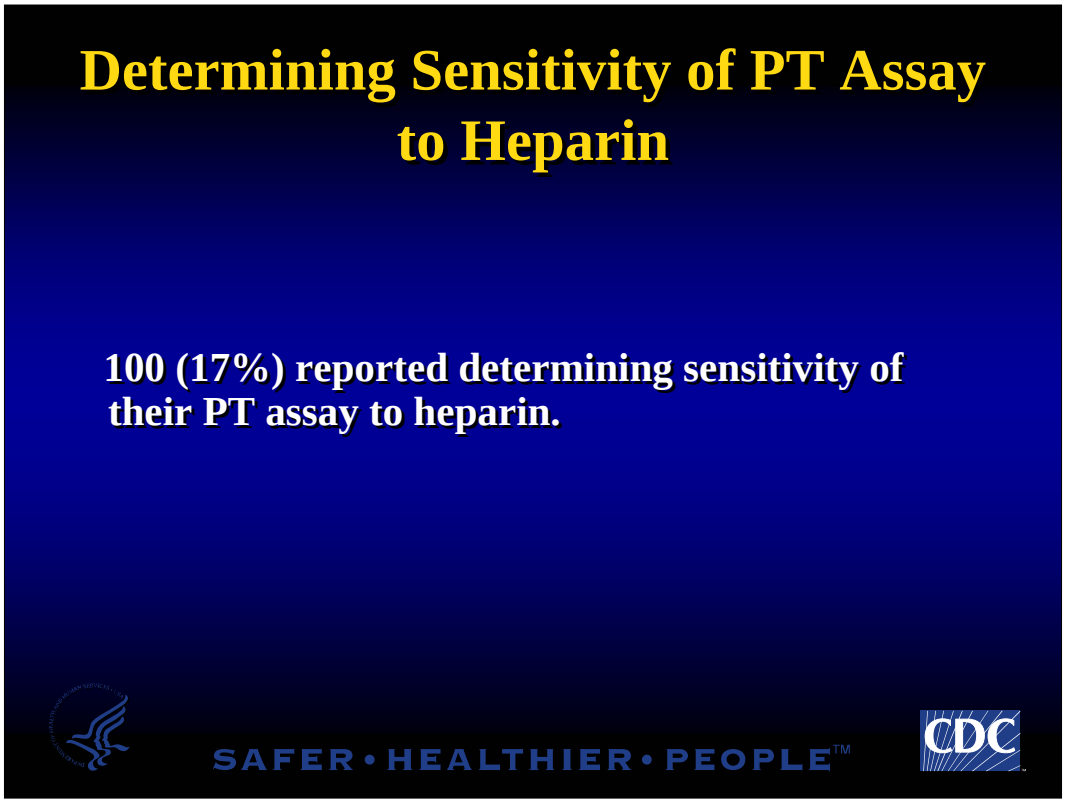
This slide shows how respondents stated reporting PT results in this survey in comparison with 2 surveys of Canadian medical laboratories in 1992 and 1996.

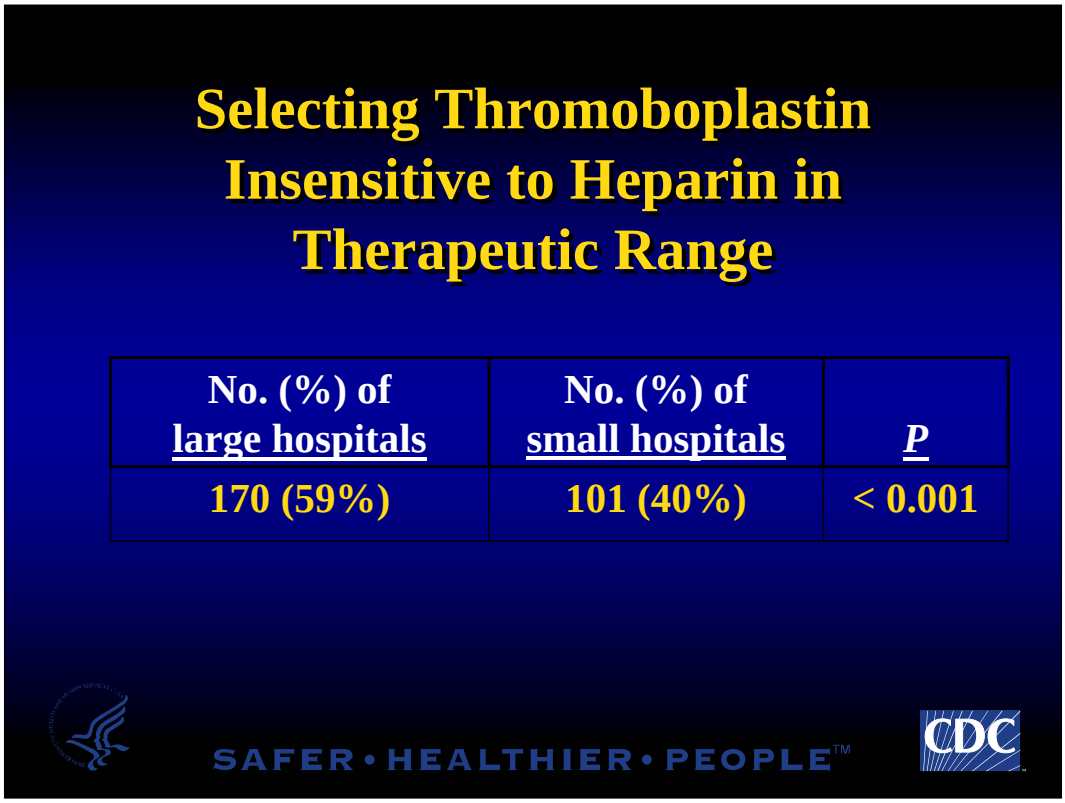
We can see a temporal increase in reporting PT results as INR and seconds. A larger proportion of Canadian laboratories report PT as INR only.



College of American Pathologists recommends that laboratories determine sensitivity of their PT assay to heparin, and where possible, select a thromboplastin that is insensitive to heparin in the therapeutic range. In agreement with the 1st recommendation, …



… 17% of the respondents reported determining sensitivity of their PT assay to heparin. Consistent with the 2nd recommendation, …

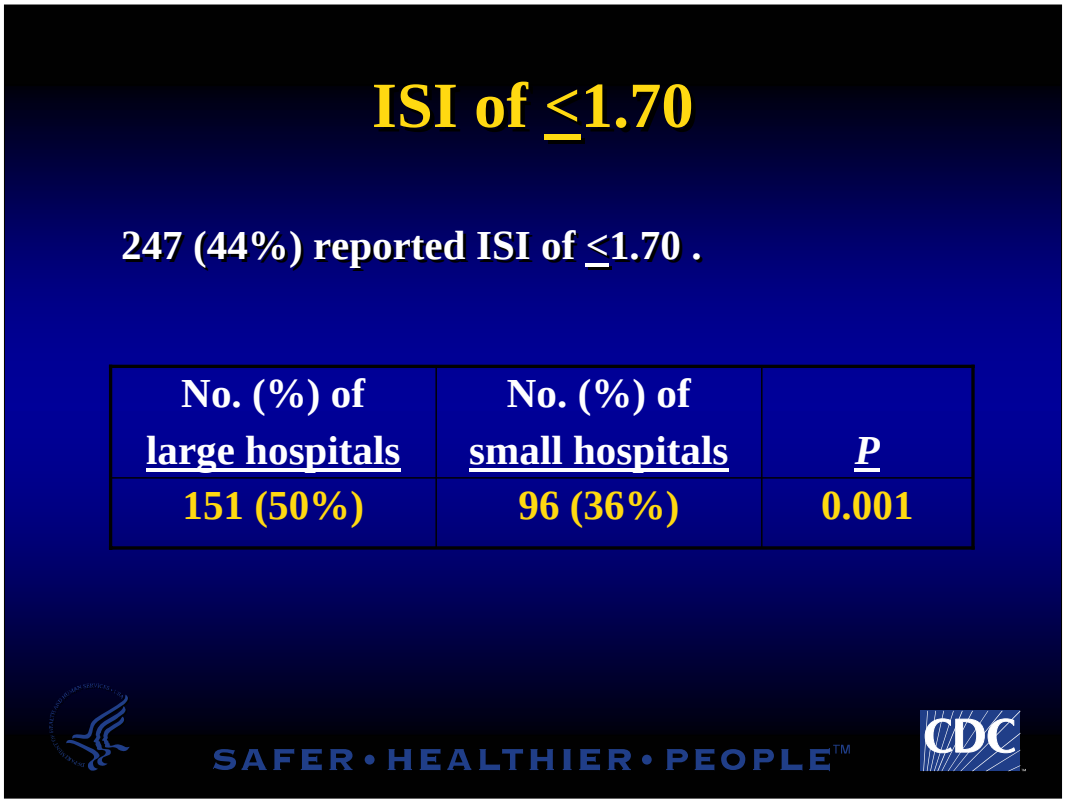


… ~50% of all respondents selected thromboplastins that were insensitive to heparin in the therapeutic range.

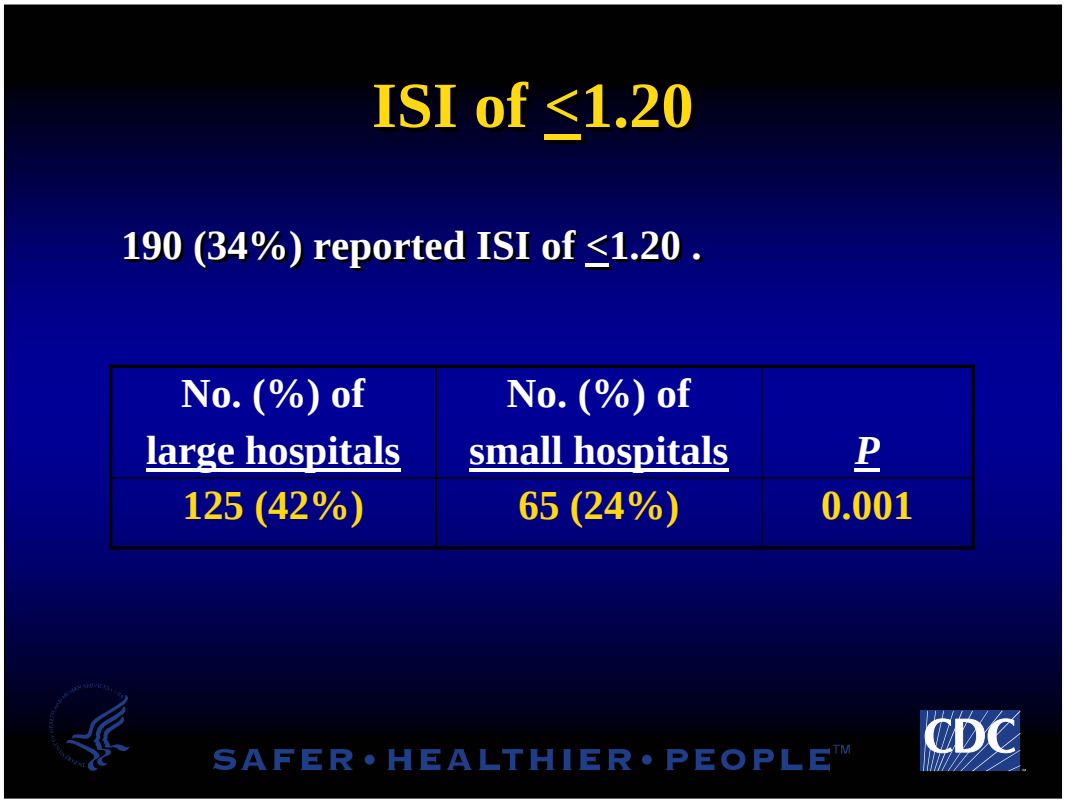
Responses from large and small hospitals were significantly different. While ~60% of large hospitals reported selecting insensitive thromboplastins, 40% of small hospitals reported doing so.

Due to the increased variability in INR resulting from ISI values deviating significantly from unity, various groups have recommended using thromboplastins with ISIs closer to 1.

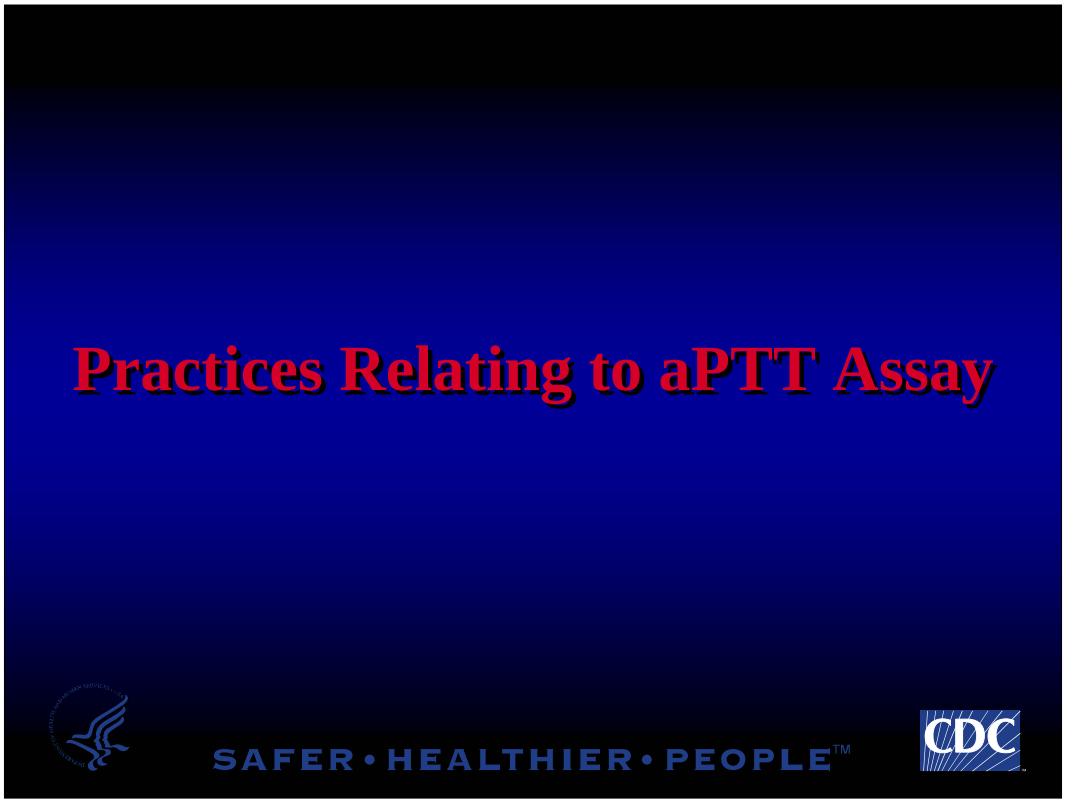
CAP recommends thromboplastins with ISIs not exceeding 1.70, while American College of Chest Physicians recommends ISIs not in excess of 1.20. Consistent with CAP recommendation, …



… 44% reported ISIs of less than 1.71 for their current thromboplastin lots. A significantly greater proportion of large hospitals reported ISIs of less than 1.71 compared to small hospitals. In agreement with recommendation of the American College of Chest Physicians, …



… 34% reported ISIs of less than 1.21 for their current thromboplastin lots. Again, a significantly greater proportion of large hospitals reported ISIs of less than 1.21 compared to small hospitals.


Practices Relating to aPTT Assay
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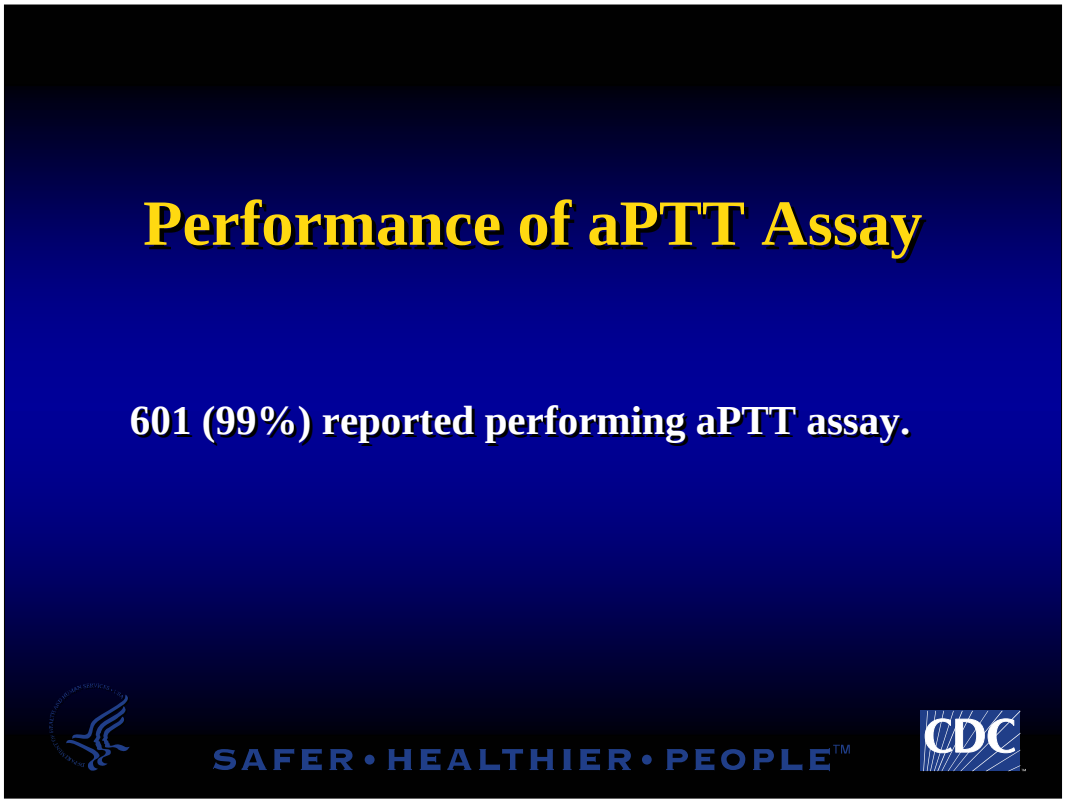
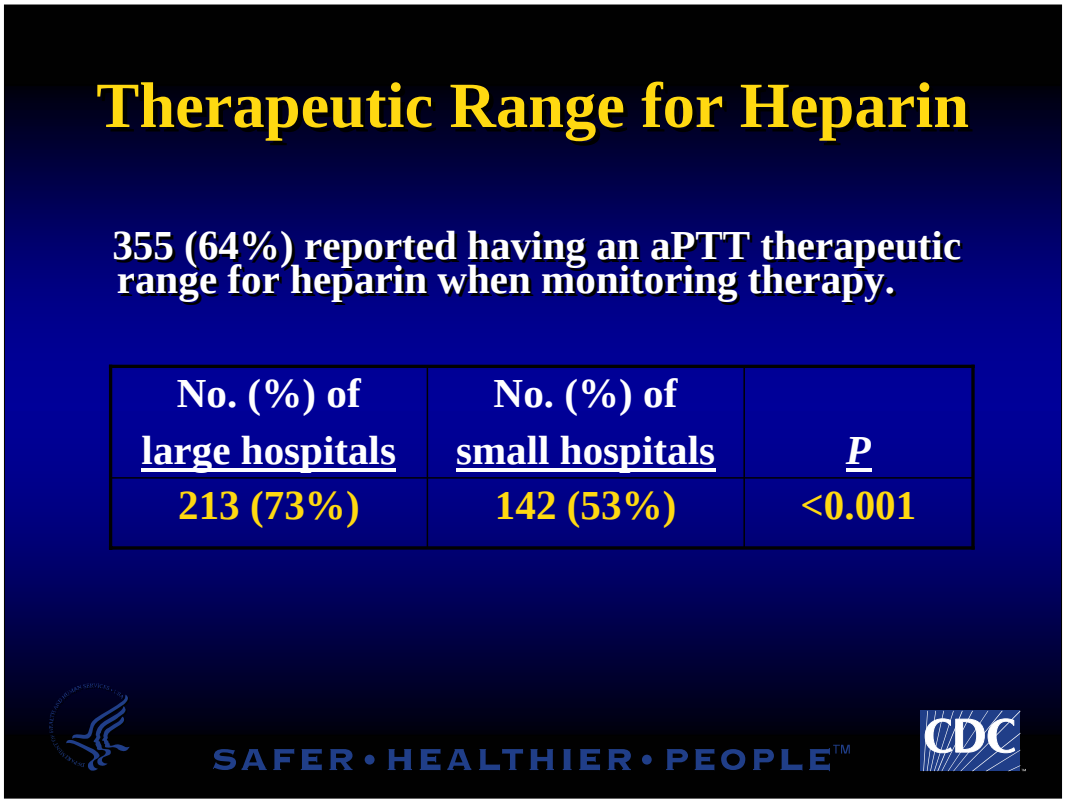
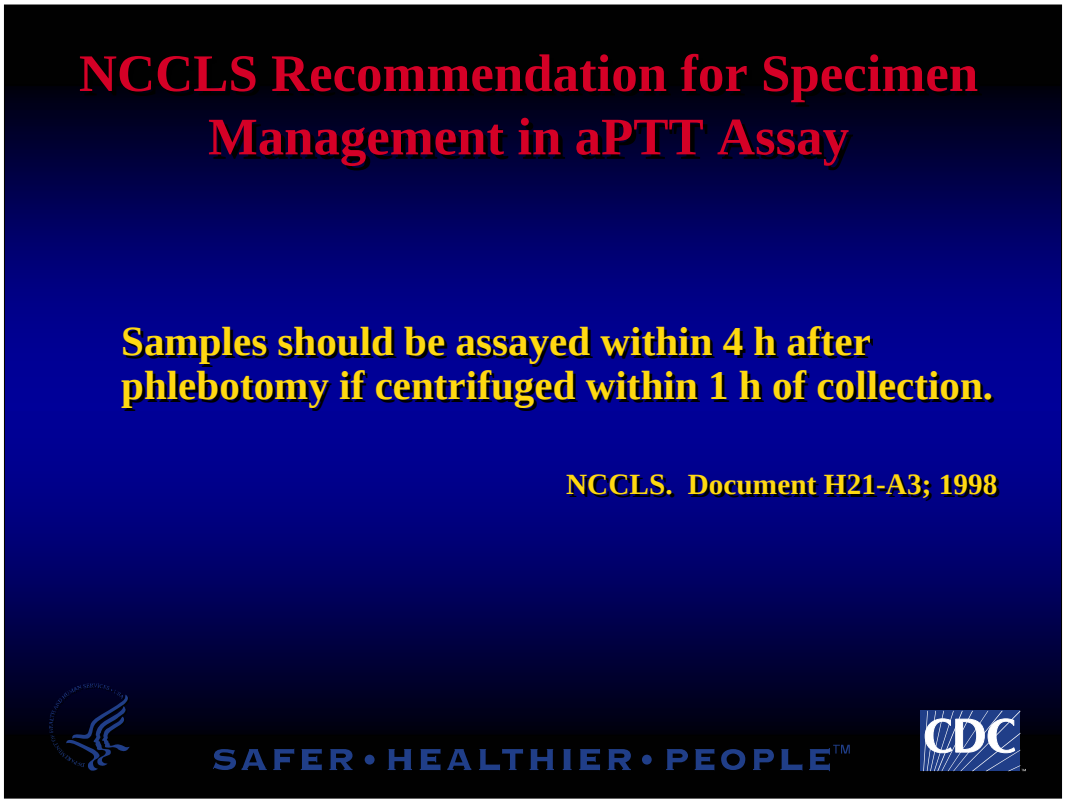


99% reported performing aPTT assay.

Based on current recommendations, each laboratory should establish an individual therapeutic range for heparin specific to its own reagent and instrument system. In agreement with these recommendations, …



… 64% reported having an aPTT therapeutic range for heparin when monitoring heparin therapy. A significantly greater proportion of the large hospitals reported doing so compared to the small hospitals. Half of the small hospital respondents reported not having an aPTT therapeutic range for heparin.



NCCLS recommends assaying samples for aPTT within 4 hours after phlebotomy if specimens are centrifuged within 1 hour of collection. In agreement with this recommendation …

Specimen Management for aPTT Assay

Practices used for aPTT assay specimen management	Large hospitals	Small hospitals	*P*
Specimens assayed within 4 h after phlebotomy	276 (96%)	259 (97%)	0.490
Specimens centrifuged within 1 h of collection	229 (84%)	238 (92%)	0.007
Specimens kept at room temperature prior to testing	223 (84%)	196 (80%)	0.188
Specimens kept at 4 °C prior to testing	47 (20%)	54 (24%)	0.335

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… more than 95% reported assaying samples for aPTT within 4 hours after phlebotomy, and ~90% reported centrifuging specimens within 1 hour of collection. A significantly greater proportion of small hospitals reported centrifuging specimens within 1 hour of collection compared to large hospitals.

~80% reported keeping specimens at room temperature before aPTT assay while ~20% reported keeping specimens at 4 °C.

Practices Relating to Monitoring of Low Molecular Weight Heparin (LMWH) Therapy

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Monitoring of LMWH Therapy

82 (14%) reported monitoring LMWH therapy:

No. (%) of large hospitals	No. (%) of small hospitals	*P*
55 (19%)	27 (10%)	0.002

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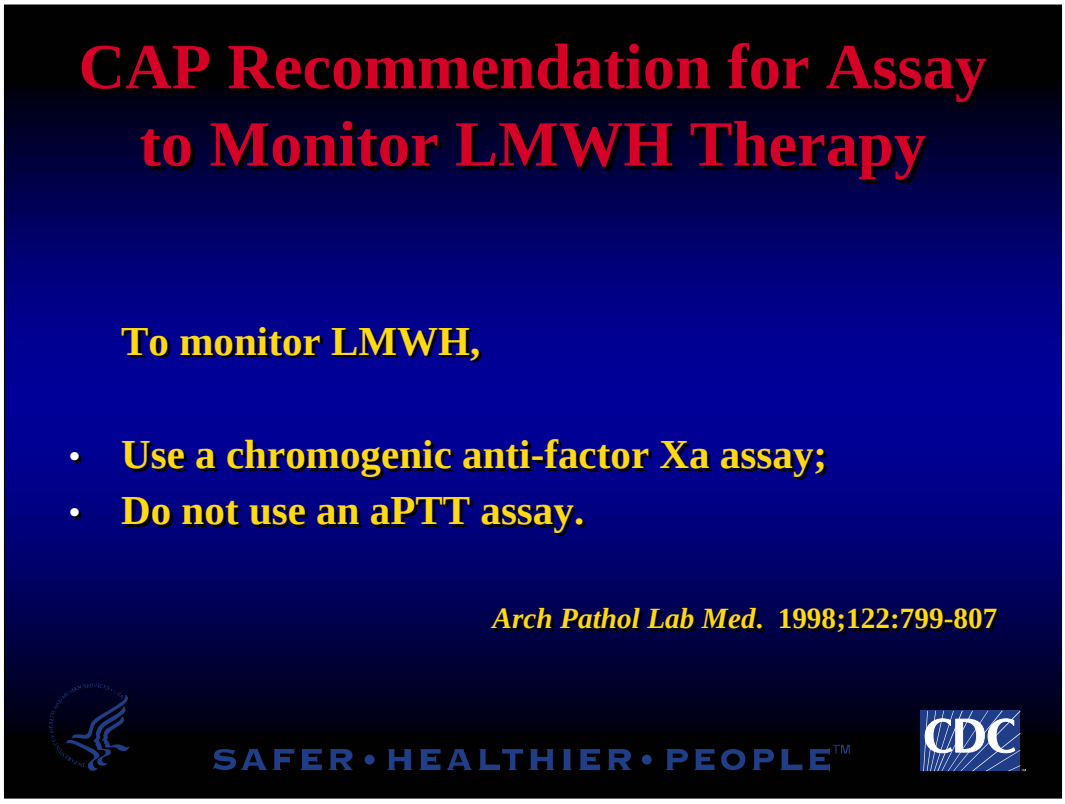
14% reported monitoring low molecular weight heparin therapy. A significantly greater proportion of large hospitals did so compared with small hospitals. However, we don't have denominator data in that we didn't ask respondents if they actually used low molecular weight heparin therapy before asking them if they monitored for it.



To monitor low molecular weight heparin, CAP recommends using a chromogenic anti-factor Xa assay and against using an aPTT assay.

Assays Used to Monitor LMWH Therapy

Assay to monitor LMWH therapy	No. (%) of large hospitals	No. (%) of small hospitals	*P*
aPTT	23 (58%)	24 (96%)	0.001
Anti-Xa	32 (65%)	3 (18%)	0.001
Factor Xa (inhibitor assay)	3 (8%)	1 (6%)	0.795
Thrombin inhibitor assay (HEP test)	0	0	–

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A significantly greater proportion of large hospitals performed *anti-Xa assay*, in agreement with CAP recommendation, to monitor low molecular weight heparin compared with small hospitals.

A significantly greater proportion of small hospitals performed *aPTT assay*, in disagreement with CAP recommendation, to monitor low molecular weight heparin compared with large hospitals.

The apparent reason small hospitals mostly used aPTT assay in lieu of anti-Xa assay to monitor low molecular weight heparin therapy may be that few of them even perform an in-house anti-Xa assay as we have documented in this survey.

Comments

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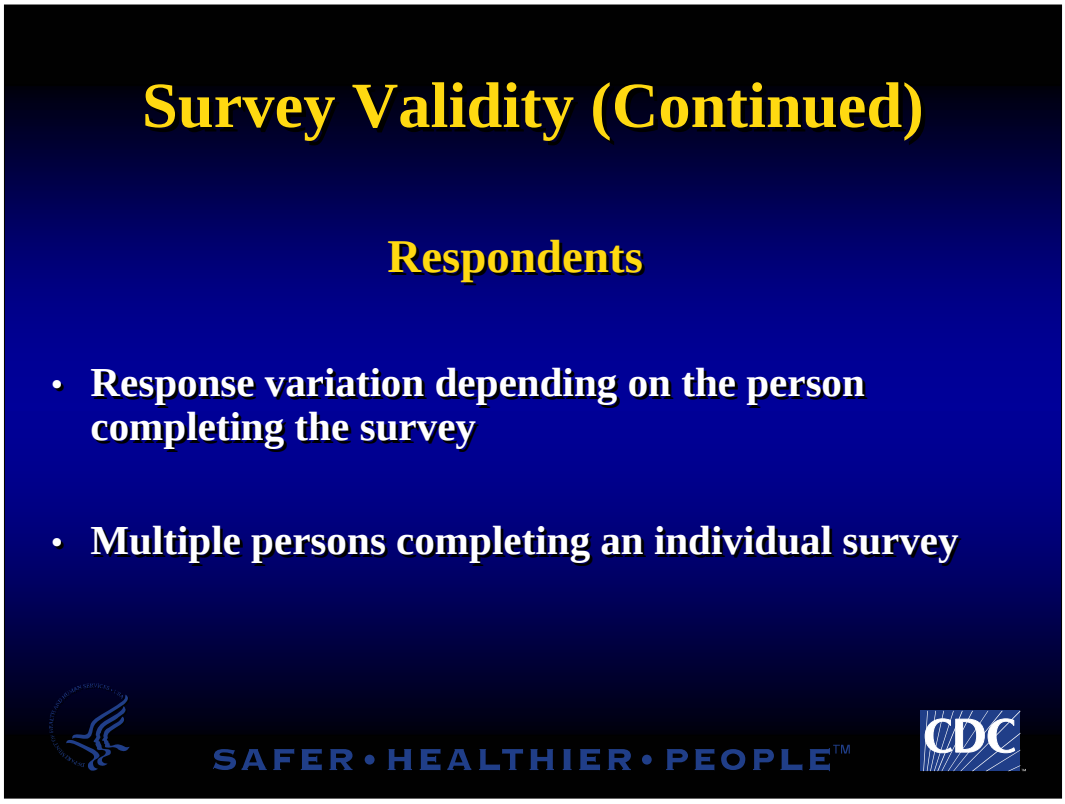
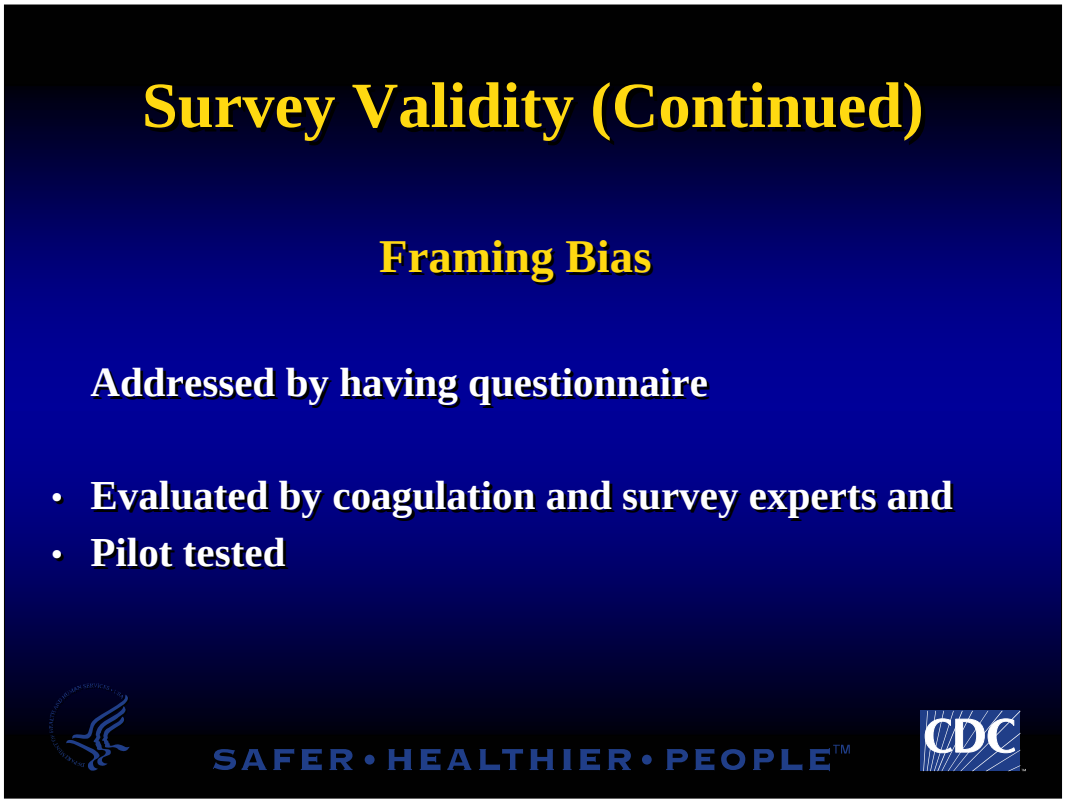
An inherent limitation of this and any other survey is that responses may not consistently reflect actual practices.

Because of the high response and sampling rates, the findings of this survey are expected to reflect well the state of reported coagulation laboratory practices in US hospitals in 2001.

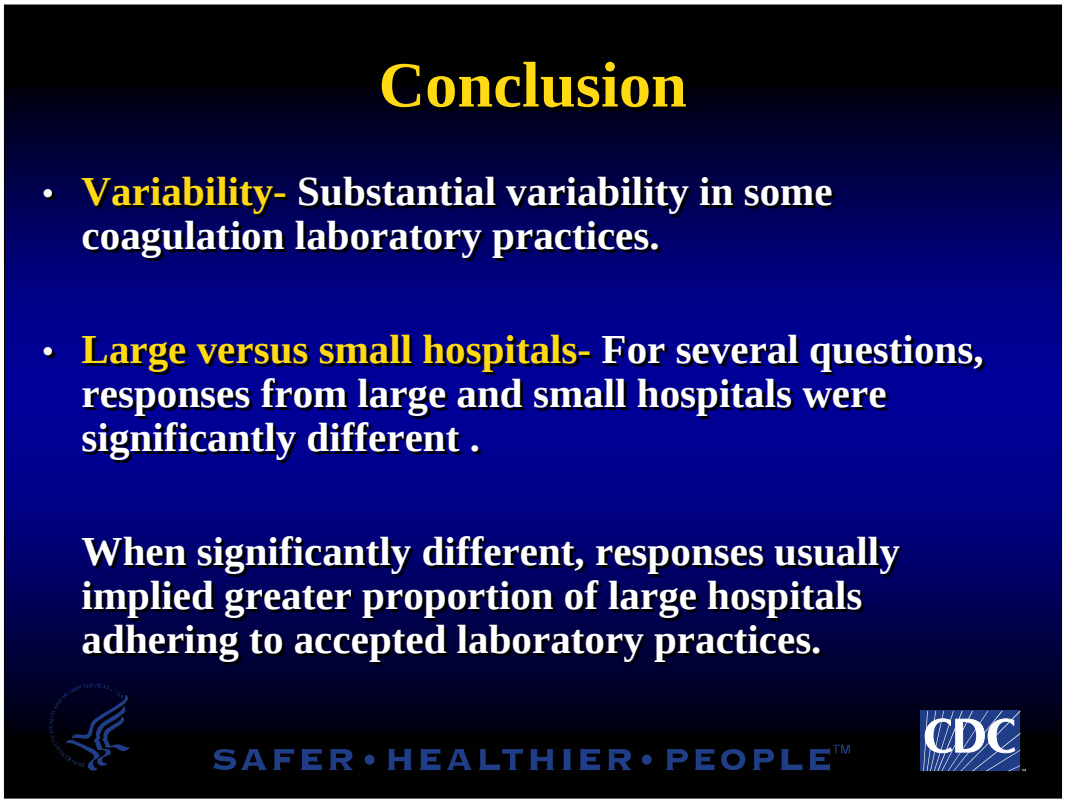


We didn't capture data on the actual individual or individuals responding at each hospital, and we also did not devise any mechanisms—for practical reasons—to assess intra- and inter-respondent reliabilities within the same institution.



Like any other survey, this instrument is subject to framing bias. It is well known that the way a question is posed (or framed) may have a dramatic impact on the response. We did attempt to reduce framing bias by having the questionnaire evaluated by survey methodologists and coagulation experts as well as by testing versions of the survey by 9 hospital coagulation laboratories.

We excluded from the sampling frame hospitals participating in pilot testing and also hospitals of the coagulation experts serving as consultants in development of the questionnaire.

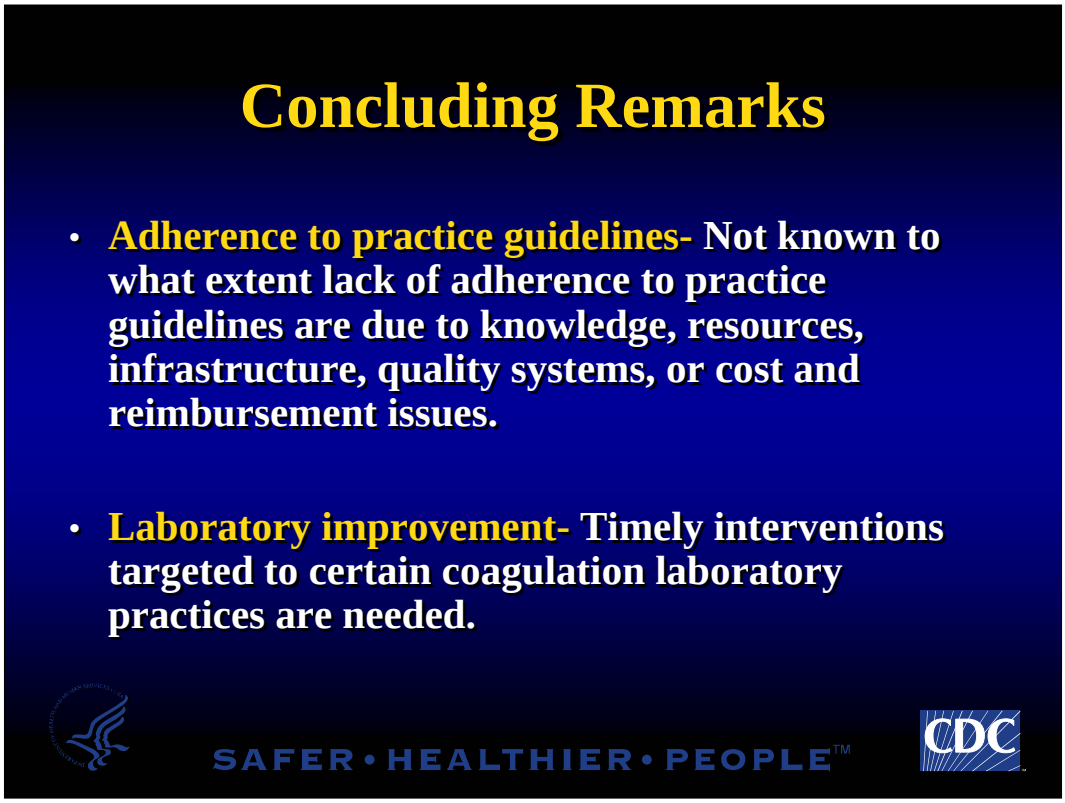


In conclusion …

This survey showed that there were substantial variabilities in some coagulation laboratory practices.

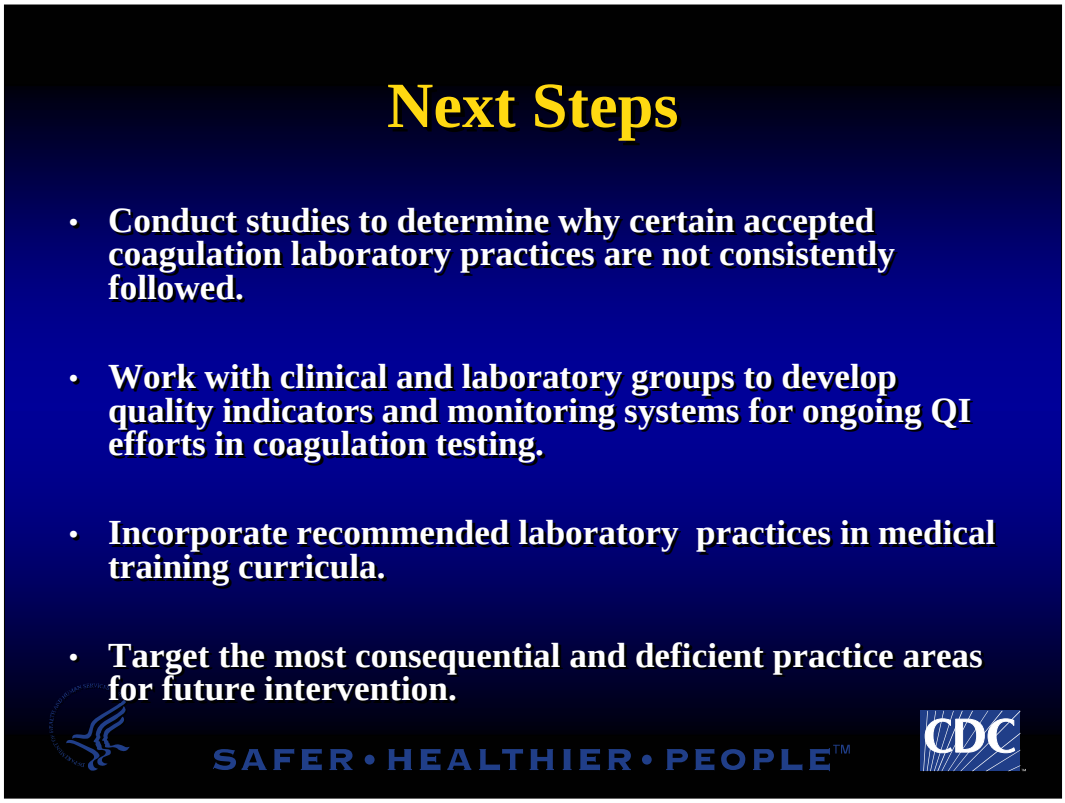
Although in most cases, response patterns from large and small hospitals were not significantly different, several questions solicited significantly different responses from these 2 groups.

When there were significant differences, usually a greater proportion of large hospitals adhered to published laboratory practice recommendations and guidelines.



We don't know to what extent not following practice recommendations and guidelines are due to knowledge, resources, infrastructure, quality systems, cost and reimbursement issues.

These data suggest a need for timely interventions targeted for improvement of certain coagulation laboratory practices.



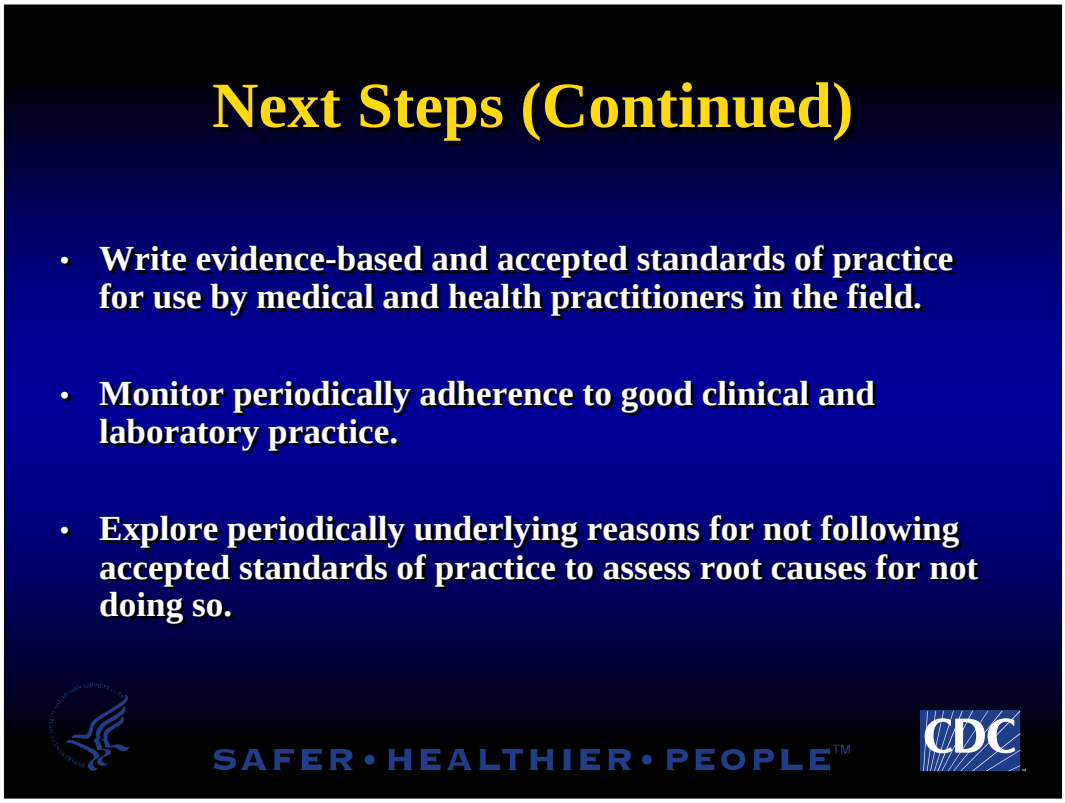
Where should laboratorians go from here?

As a vital component of the health care delivery system, we should conduct studies to understand why certain accepted coagulation laboratory practices are not consistently followed;

We should work with clinical and laboratory groups to develop quality indicators and monitoring systems for ongoing quality improvement efforts in coagulation testing;

We should work with our clinical colleagues to incorporate recommended laboratory practices in medical training curricula;

We should target the most consequential and deficient practice areas for future intervention. These efforts should include dissemination of practice guidelines and administration of periodic surveys to not only assess but also lead change in improved practice patterns over time.



Publication and dissemination of practice guidelines may be necessary but not sufficient for quality improvement in medical and laboratory practice.

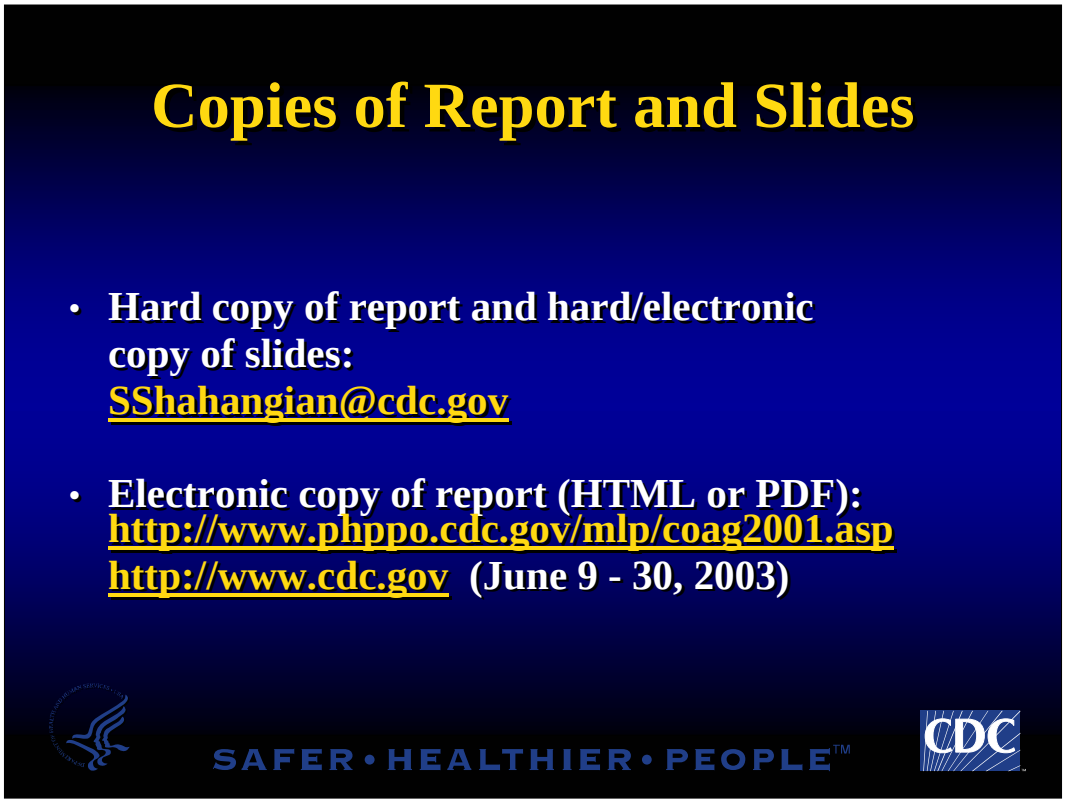
•Evidence-based and accepted standards of practice should be written for use by medical and health practitioners in the field;

•Adherence to good clinical and laboratory practice should be periodically monitored; and

•Underlying reasons for not following accepted standards of practice should be periodically explored to determine the root causes such as lack of knowledge, resources, infrastructure, quality systems, cost and reimbursement issues.

This study would not have been possible had it not been for the contributions of numerous colleagues, many of whom are not listed in this limited space; and I like to take this opportunity to thank them.

Finally, I want to thank you for your attention and for your interest.



You can download the full report of this survey at this URL. This site went live in February, and was also noted as a spotlight on CDC's home page last week. This site will again go on CDC's home page during the last 3 weeks of this month beginning on June 9.

Now, I am pleased to take the 1st question or comment.