

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Studdert DM, Mello MM, Gawande AA, et al. Claims, errors, and compensation payments in medical malpractice litigation. *N Engl J Med* 2006;354:2024-33.

TECHNICAL APPENDIX

The manuscript briefly describes: (a) the clinical categories the study focused on; (b) the way in which the sample was drawn; (c) what information is actually in claim files; and (d) the sensitivity analyses. We elaborate on those issues here.

A. Clinical Category Definitions & Method for Resolving Overlapping Definitions

A **surgical claim** was defined as one involving an operation, care related to an operation, or an alleged failure to provide a timely and appropriate operation. We excluded injuries due to medical treatment or procedures (e.g. cardiac catheterizations, endoscopy, and interventional radiology procedures); anesthesia-related claims (unless they overlapped with a surgical claim); claims in which the main allegation was defective equipment or devices; and claims related to abortions or dilation and curettage.

Claims involving **missed or delayed diagnosis** were defined as those alleging an error in diagnosis or testing that caused a delay in appropriate treatment, or a failure to act or follow-up on diagnostic test results. We excluded allegations related to pregnancy. Claims pertaining to care rendered solely in the inpatient setting were also excluded. We focused on outpatient claims because of their high prevalence and perceived importance to both patient safety research and medical malpractice policy.

An **obstetrical claim** was defined as one that involved a mother or infant (fetus/newborn) and occurred during the prenatal, intrapartum or immediate post-partum period. This included delays in diagnosing maternal or fetal conditions, and operative or anesthesia complications that occurred during pregnancy, labor, or delivery. We excluded claims related to abortions or dilation/cutrage, ectopic pregnancy, and early stages of assisted reproductive technology in which the main allegations related to the technology or its use.

A **medication-related claim** was defined as one in which the allegation pertains to a medication process, including alleged errors in prescribing, transcribing, dispensing, administering, or monitoring of a medication. It may also include an alleged omission or failure to order a medication on a protocol or guideline.

This included allegations of:

- ◆ Wrong drug, dose, frequency, or route
- ◆ Inappropriate or inadequate monitoring after medication administration
- ◆ Clinically inappropriate drug choice by physician
- ◆ Medication prescribed that has drug interaction or to which patient has an allergy or other contraindication
- ◆ Inadequate patient education about a drug or regimen

This excluded allegations of:

- ◆ Problems with intravenous (IV) lines or vascular access issues

Guide for Categorizing Claims That Meet More Than One Clinical Category Definition

	<i>Obstetric claim</i>	<i>Operative claim</i>	<i>Medication-related claim</i>	<i>Missed/delayed diagnosis claim</i>
<i>Obstetric claim</i>		Categorize as Obstetric	Categorize as Medication-related, unless · the allegation is fundamentally tied to an issue of obstetrical management, categorize as Obstetric	Categorize as Obstetric
<i>Operative claim</i>	Categorize as Obstetric		Categorize as Medication-related, unless · <i>also</i> meets definition of Obstetric, then categorize as Obstetric	Categorize as Missed/delayed, unless · <i>also</i> meets definition of Obstetric, then categorize as Obstetric · <i>also</i> meets definition of Medication-related, then categorize as Medication-related · <i>also</i> meets definition of both Obstetric and Medication-related, then categorize as Obstetric
<i>Medication-related claim</i>	Categorize as Medication-related, unless · the allegation is fundamentally tied to an issue of obstetrical mgt, then categorize as Obstetric	Categorize as Medication-related, unless · <i>also</i> meets definition of Obstetric, then categorize as Obstetric		Categorize as Medication-related
<i>Missed/delayed diagnosis claim</i>	Categorize as Obstetric	Categorize as Missed/delayed, unless · <i>also</i> meets definition of Obstetric, then categorize as Obstetric · <i>also</i> meets definition of Medication-related, then categorize as Medication-related · <i>also</i> meets definition of both Obstetric and Medication-related, then categorize as Obstetric	Categorize as Medication-related	

B. Sampling and Claims File Review

The manuscript states that “Insurers contributed to the study sample in proportion to their annual claims volume.” This is a simplification of a more involved sampling and review process. Retrieval and review of claims files and their associated medical records was an expensive and extremely labor-intensive process. It proceeded as follows:

1. Based on pilot work conducted at two insurers in retrieving and reviewing claims files, we calculated that study resources permitted approximately 1500 completed reviews. This became our **overall study target**.
2. Individual **site targets** were set by taking each insurer’s average annual caseload during the previous five years (x) and dividing it by the sum of the five averages (y) to calculate the site’s contribution to the overall study target ($x/y * 1500$). The table shows the final site targets.

Insurer	Site Targets	Reviews Completed	Clinical Categories Covered
Site 1	672	662	Ob, diagnostic, medication, surgery
Site 2	302	294	Ob, diagnostic, medication, surgery
Site 3	87	84	Diagnostic, medication, surgery
Site 4	98	95	Ob
Site 5	341	317	Ob, diagnostic, medication, surgery
<i>Total</i>	<i>1500</i>	<i>1452</i>	

3. The table also shows that 3 sites contributed claims in all clinical areas. One site had no obstetrics claims (a reflection of the services its insured individuals/facilities provided). And one site agreed to allow access to its obstetrics claims only (due to its special interest in this area).
4. Next we worked with insurers to identify closed claims that met the clinical category definitions. This was an arduous process because the insurers’ administrative databases generally did not allow a conclusive determination as to whether a particular claim met one of the study’s clinical category definitions prior to retrieval of the claims file from storage. Therefore we created candidate lists within each clinical category at each site, starting with the most recently closed claims and moving back in time. We reviewed narrative summaries of all candidate claims, and retrieved any that appeared to meet our study definitions. Study staff made a final determination of claim’s eligibility by examining the hardcopy claim file. After a claim’s eligibility was confirmed, we retrieved the associated medical record from the relevant institution and gave the set of documents to the physician reviewer for review.
5. We began with the most recently closed claims and moved back in time (i.e. down the candidate list)—retrieving claims and records, confirming their definitional eligibility, and having them reviewed—until the target number at each site was

reached. For 48 claims, it was not clear until during or after the physician review that the claim was ineligible. Therefore we fell slightly short of our overall study target.

C. What Is In A Claims File?

The claims file captures a wide variety of data, including the statement of claim, depositions, interrogatories, and other litigation documents; reports of internal investigations; expert opinions from both sides; medical reports detailing the plaintiff's pre- and post-event condition; and, while the claim is open, medical records pertaining to the episode of care at issue. The file may not contain some of these documents if the claim was dropped or settled early in the process.

D. Sensitivity Analyses

The two sensitivity analyses we conducted are briefly described in the manuscript.

(i) Exclusion of the close calls (n=339)

This slightly increased the proportion of claims without errors to 40% (430/1065) and had trivial effects on the magnitude and statistical significance of differences between non-error and error claims shown in Table 2, with one exception: there were now disproportionately fewer medication injuries among non-error claims than error claims (14% vs 20%, $P=0.01$).

(ii) Exclusion of the clinical categories with relatively low reliability (n=746)

We also reran the main analyses excluding the two clinical categories—obstetrics and diagnosis—that had the lowest inter-rater reliability for the error determination. The proportion of claims with errors in the reduced sample was nearly identical (64%, 421/658). The profile of defendant specialties changed and mean payment values decreased (because obstetric and diagnostic claims attracted the highest payments on average). In addition, there was no longer a significant difference between mean payments levels for non-error and error claims. All other results from Table 2 were essentially unchanged.