# Regulatory approval of new medical devices: cross sectional study

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## ABSTRACT

### OBJECTIVE

To investigate the regulatory approval of new medical devices.

### DESIGN

Cross sectional study of new medical devices reported in the biomedical literature.

### DATA SOURCES

PubMed was searched between 1 January 2000 and 31 December 2004 to identify clinical studies of new medical devices. The search was carried out during this period to allow time for regulatory approval.

### ELIGIBILITY CRITERIA FOR STUDY SELECTION

Articles were included if they reported a clinical study of a new medical device and there was no evidence of a previous clinical study in the literature. We defined a medical device according to the US Food and Drug Administration as an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article."

### MAIN OUTCOME MEASURES

Type of device, target specialty, and involvement of academia or of industry for each clinical study. The FDA medical databases were then searched for clearance or approval relevant to the device.

### RESULTS

5574 titles and abstracts were screened, 493 full text articles assessed for eligibility, and 218 clinical studies of new medical devices included. In all, 99/218 (45%) of the devices described in clinical studies ultimately received regulatory clearance or approval. These included 510(k) clearance for devices determined to be "substantially equivalent" to another legally marketed device (78/99; 79%), premarket approval for high risk devices (17/99; 17%), and others (4/99; 4%). Of these, 43 devices (43/99; 43%) were actually cleared or approved before a clinical study was published.

### CONCLUSIONS

We identified a multitude of new medical devices in clinical studies, almost half of which received regulatory clearance or approval. The 510(k) pathway was most commonly used, and clearance often preceded the first published clinical study.

## WHAT IS ALREADY KNOWN ON THIS TOPIC

New medical devices have distinct regulatory approval pathways

## WHAT THIS STUDY ADDS

Almost half of the new medical devices described in the literature ultimately receive regulatory clearance or approval

The 510(k) pathway (a fast track system allowing regulatory approval of a device that is "substantially equivalent" to a predicate device) is most commonly used, and clearance often precedes the first published clinical study

## Introduction

The introduction of new medical devices is fundamental to the advancement of healthcare. Historically, such devices have been adopted with little scientific evidence to support their use.[1] Although many devices have greatly improved clinical outcomes, not all are beneficial and some may be harmful. To this end most jurisdictions have developed regulatory bodies, such as the US Food and Drug Administration, that ensure the safety and effectiveness of new medical devices.[2] These regulatory bodies must also act in an efficient and timely manner such that patients are not deprived from beneficial innovations.

The process by which new high risk medical devices find their way from bench to bedside is well established: the development of the device resulting in a first-in-human study; the evaluation of the device in clinical trials, culminating in a regulatory approval for use; and the adoption of the device.[3] Although high risk devices warrant considerable scientific evidence for their safety and effectiveness before regulatory approval, the pathway for lower risk devices is less stringent, allowing for their more rapid approval.[4-6]

We investigated the use of these distinct regulatory approval pathways for new medical devices.

## Methods

We performed a cross sectional study of new medical devices reported in the literature to determine whether they received regulatory approval, and the relative contributions of academia and industry in this process. Before searching for evidence of regulatory approval, we identified clinical studies of devices, allowing us to capture those devices that failed to receive approval.

We defined a medical device according to the FDA definition as an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article." If there was no evidence of a previous clinical study of a device in the literature, we considered the device as new.

For each article reporting a clinical study of a new medical device, we defined academia and industry as being involved with the development of the device if a relation was described. If an entry could be found on the FDA medical device databases, we considered a device as having regulatory approval.

### Search strategy

The PubMed database was searched using the Boolean term: (device OR instrument OR apparatus OR implant OR "in vitro reagent" OR system) AND ("first in man" OR "first in human" OR "first experience" OR "first clinical" OR "early clinical" OR "early experience" OR "early human" OR "initial experience" OR "initial