AANA Journal Course No. 6
Examination Information

Quality assurance

With this issue of the AANA Journal, the sixth course on "Quality assurance" has been completed. The course consisted of a six-part series, beginning with the April, 1986 issue and concluding in the February, 1987 issue. The series was published as follows:

- Part 1—(April, 1986)—Quality assurance: The pieces of the puzzle
- Part 2—(June, 1986)—Quality assurance: A unit-based plan
- Part 3—(August, 1986)—Quality assurance: Prevention and management of anesthetic mishaps
- Part 4—(October, 1986)—Quality assurance: The law
- Part 5—(December, 1986)—Quality assurance: Medical malpractice—The need for documentation/communication
- Part 6—(February, 1987)—Quality assurance: FDA approval and surveillance of medical devices

Each article included a self-assessment quiz, along with a suggested reading list for reference and study.

The examination printed in this issue incorporates material from all six articles. The examination consists of 60 multiple-choice questions, 10 questions from each article. The examination is clearly marked as to which questions refer to which article. Remember, as you are taking the examination, you are free to refer back to the original articles. Note also that there is but one correct answer to be marked for each question.

About your Continuing Education Credit...

To ensure that a certain level of knowledge has been attained, a minimum of 70% correct answers (42 out of 60) must be achieved. A total of 6 hours of Continuing Education (CE) Credit will be awarded for the successful completion of the examination; partial continuing education credit will not be awarded.

Only those passing the examination will be notified by mail of the successful completion of the course. (The time of this mailing will be dependent on the volume of response; however, notification will be effected prior to the close of the CE Year—July 31, 1987.) AANA members will automatically have their 6 CE Credits recorded for them. Individuals with record-keeping contracts through the AANA will also have the credits recorded for them.

The correct answers to the examination will appear in the August, 1987 issue of the AANA Journal. By keeping a copy of your answers, you will automatically be able to see how you scored.

How to fill out the answer sheet...

It is recommended that you first mark your answers on the examination itself (so that you have your own record). Then, transfer your answers in pencil to the answer sheet, which appears on the other side of this page. Be sure to include your name, address, and AANA identification number. (Non-AANA members should include a $30 tuition fee—payable to the AANA: Journal Course—along with their examination answer sheet.)

Important deadline...

The examination answers must be post-marked by June 19, 1987. Adequate time must be allowed for the examination to be processed to ensure that all CE Credits are recorded prior to the end of the CE year. Mail your answer sheet to:

American Association of Nurse Anesthetists
216 Higgins Road
Park Ridge, Illinois 60068-5790
Attn: Journal Course

Much success...

We hope that you have found this sixth AANA Journal course to be of value. We wish you well in its successful completion.
American Association of Nurse Anesthetists
216 Higgins Road
Park Ridge, Illinois 60068

AANA Journal Course No. 6 Examination
Quality assurance
(Issued April, 1987)

Please PRINT.

Name:
(last)

(first)

(middle)

Address:
(street)

(city)

(state)

(zip code)

AANA Membership ID Number:

☐ □ If you are not an AANA member, check here. Be sure to enclose your $30 tuition fee payable to AANA.

Please circle one response for each question.
For example, 36. 1 2 3 4 would indicate that the third alternative was chosen in response to question 36.

Please erase completely any changed responses.

1. 1 2 3 4
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30. 1 2 3 4

AANA Code No. 8644; Expiration date June 19, 1987
1. A quality assurance program should begin with the:
   1. development of standards
   2. identification of values
   3. statement of purpose
   4. stated objectives

2. The current hallmark of any QA program is:
   1. the chart audit mechanism
   2. the peer review process
   3. the process of addressing specific problems
   4. ongoing monitoring and evaluation

3. Within the last few years, QA innovations have included a strong impetus toward:
   1. problem identification
   2. audits
   3. decentralization
   4. peer review

4. Accountability for any QA program rests solely with the:
   1. individual practitioner
   2. Professional Standards Review Organization (PSRO)
   3. Joint Commission on Accreditation of Hospitals (JCAH)
   4. individual institutions

5. A desired level of performance against which actual performance can be measured best defines:
   1. norm
   2. standard
   3. criterion
   4. value

6. Criteria, predetermined factors against which standards are measured, are usually related to which facet of health care delivery:
   1. structure
   2. outcome
   3. process
   4. all of the above

7. A criterion which states "Prior to administering an anesthetic, all equipment will be checked to ensure proper functioning" is an example of an:
   1. structure criterion
   2. outcome criterion
   3. process criterion
   4. retrospective criterion

8. The type of criteria most commonly used to evaluate the effectiveness of the care provider is:
   1. structure
   2. outcome
   3. process
   4. audit

9. A QA data base is best established using:
   1. auditing and credentialing
   2. interviewing and observing
   3. surveys and questionnaires
   4. all of the above

10. Credentialing of health care workers addresses which type of QA criteria:
    1. audit
    2. structure
    3. outcome
    4. process
11. JCAH recommends a quality assurance monitoring system which is:
   1. monthly
   2. semi-annually
   3. ongoing and continuous
   4. used only when problems arise

12. A comprehensive departmental QA monitoring system should include the following:
   1. specific data collection mechanisms
   2. appropriate critical indicators
   3. realistic timetable for data collection
   4. all of the above

13. The initial step in developing a unit-based QA plan is:
   1. establishing a QA committee
   2. developing a QA plan
   3. defining critical indicators
   4. devising monitoring checklists

14. The phase of peer review marked by trial and error responses is:
   1. internalization
   2. utilization
   3. familiarization
   4. routinization

15. Which of the following is not characteristic of the Internalization Phase of peer review:
   1. non-threatening departmental climate
   2. frequent on-site hands-on evaluations
   3. negative findings acted upon
   4. objectives usually ambiguous

16. A potent mechanism for demonstrating accountability for practice is:
   1. peer review
   2. semi-annual chart audits
   3. patient satisfaction surveys
   4. frequent staff meetings

17. The peer review process is based on:
   1. personality traits
   2. objective standards
   3. standards established by the head of the department
   4. unwritten but widely known criteria

18. The final step in implementing a unit-based QA plan is:
   1. reporting findings to the departmental staff and the hospital QA committee
   2. evaluating the action taken
   3. selecting a new committee chairperson
   4. re-auditing all incomplete records

19. Peer review has been defined as:
   1. a monthly gripe session
   2. evaluation of clinical staff by managerial staff
   3. colleagues examining the goal-directed care of colleagues
   4. an opportunity to undermine departmental morale

20. If the QA committee is interested in determining if patients are being seen the day before surgery by a member of the anesthesia staff, an appropriate monitoring methodology might be:
   1. unstructured interview
   2. ethnographic observation
   3. questionnaire
   4. triangulation of data

21. The Critical Incident Technique was defined and developed by:
   1. Flanagan
   2. Cooper
   3. Newbower
   4. Long

22. What percent of incidents found by Cooper in his 1978 study were attributable to human error:
   1. 26%
   2. 51%
   3. 14%
   4. 82%

23. The most frequently reported anesthesia incident from Cooper's study was:
   1. syringe swap
   2. gas supply problem
   3. laryngoscope malfunction
   4. breathing circuit disconnection

24. The most frequently associated contributing factor in anesthesia mishaps was:
   1. unfamiliar equipment
   2. inexperience
   3. fatigue
   4. failure to perform a normal check

25. In Cooper's study, he found that relieving anesthesia personnel for a break was a negative factor in only:
   1. 2 situations in 15
   2. 1 situation in 10
   3. 3 situations in 20
   4. 4 situations in 20
26. The sole purpose of reporting critical incidents in your practice setting would be:
   1. to heighten awareness of preventable anesthesia mishaps
   2. to involve administration in the reporting process
   3. to punish offenders
   4. to dismiss anesthesia staff members

27. Problems identified through the investigation of an anesthetic mishap should be resolved through which of the following mechanisms:
   1. risk management report
   2. incident report
   3. departmental QA program
   4. FDA

28. Documentation is best described by which of the following items:
   1. thorough and accurate
   2. timely
   3. in accordance with departmental policy
   4. all of the above

29. When a mishap occurs, anesthetic equipment should be:
   1. suspected and checked by the anesthesia practitioner
   2. suspected and removed from service until checked by qualified biomedical technicians
   3. suspected and used with caution
   4. suspected only when defects are obvious

30. Who should be responsible for acting upon the recommendations of the peer review committee:
   1. chief executive officer
   2. risk management officer
   3. anesthesia department chairperson
   4. director of QA

31. The standard of care used by modern courts relates geographically to the standard of the:
   1. local city or town
   2. state
   3. nation
   4. hospital

32. To prevail in a negligence action the plaintiff must prove:
   1. duty, breach, causation, damages
   2. mutual assent, breach, injury, damages
   3. Res Ipsa Loquitor
   4. Respondeat Superior

33. The two parts of causation which must be demonstrated in a negligence action are:
   1. cause in fact and Respondeat Superior
   2. proximate cause and Respondeat Superior
   3. cause in fact and proximate cause
   4. cause in fact and mutual assent

34. Damages most frequently granted in a negligence action are:
   1. punitive damages
   2. general and special damages
   3. injunction
   4. specific performance

35. The rationale for application of the Doctrine of Respondeat Superior include:
   1. employee benefit from employer resources and greater employer resources
   2. indemnity and employee benefit
   3. employer benefit from employee efforts and greater employer resources
   4. the thing speaks for itself and indemnity

36. A goal of state licensure of professions is:
   1. decreased cost of health care
   2. assuring access to jobs for the professionals licensed
   3. elimination of private certification of professionals
   4. public protection through assuring minimal standards of competency

37. The case of *Jefferson Parish Hospital District No. 2 v. Hyde* held that there was no anticompetitive effect from an exclusive contract between anesthesia care providers and a hospital if:
   1. the contract was express, implied in fact, or implied in law
   2. anesthesia care from different, competing providers was available to patients at nearby facilities
   3. the contract does not preclude CRNAs from providing anesthesia care in the facility
   4. the contract does not preclude physicians from providing anesthesia care at the facility

38. The following individuals meet the criteria to bring an antitrust action:
   1. any nurse against any hospital administrator
   2. a member of a class participating in the same market as the defendant
   3. the employee under the Doctrine of Respondeat Superior
   4. any physician against any nurse
39. The 9th Circuit Federal Appellate Court in *Bahn v. N.M.E. Hospitals, Inc.* stated that one reason this nurse anesthetist could bring an action against the defendants was because under antitrust law:
   1. he did compete in the same market as the defendant anesthesiologists even though physician supervision and direction was required for his practice
   2. he did compete because no physician supervision and direction was required in his practice
   3. it doesn't matter whether the plaintiff and defendant compete in the same market
   4. professions are not subject to antitrust law

40. To prevail under antitrust law the plaintiff must show:
   1. an unreasonable action by the competitor/defendant in restraint of trade
   2. an action by a hospital administrator which prevents nurse anesthetists from acquiring privileges at the hospital
   3. he was unable to get a job
   4. he has sufficient malpractice insurance coverage

41. Negligence is defined as:
   1. meeting the standard of care by a reasonably prudent person
   2. exceeding the standard of care by a reasonably prudent person
   3. an act a reasonably prudent person guided by considerations which ordinarily regulate human affairs would or would not do
   4. injuring a patient where the standard of care was met

42. For a plaintiff's attorney to bring a malpractice suit against a medically trained provider, the following elements must exist:
   1. a legal duty was established, the provider's care exceeded the standard, an injury occurred
   2. a legal duty was established, the provider's care met the standard, an injury occurred
   3. a legal duty was established, the provider's care fell below the standard, an injury occurred
   4. a legal duty was established, the provider's care fell below the standard, an injury occurred, the injury was not related to the breach of duty or the substandard of care

43. Ways to deter malpractice suits by the provider are:
   1. documentation and charting
   2. charting and communication
   3. documentation and communication
   4. there is no way to deter suits

44. Documentation verifies all of the following except:
   1. patient's recall of events
   2. patient care given by the anesthesia provider
   3. informed consent of the patient
   4. provider's presence during the anesthetic

45. Documentation of the pre-anesthetic visit should include:
   1. patient's response, anesthetic plan, ASA classification
   2. patient's response, anesthetic plan, ASA classification, informed consent statement
   3. patient's response, anesthetic plan, informed consent, ASA classification, acceptance or refusal of anesthetic plan and risk of anesthesia
   4. patient's response, anesthetic plan, informed consent, risk of anesthesia, and acceptance or refusal of anesthetic plan by the patient

46. Items which should be checked and documented prior to the administration of anesthesia are:
   1. the anesthesia machine, equipment for induction, intubation, maintenance and resuscitation, patient's response to premedication, pre-induction vital signs and all monitors
   2. the anesthesia machine and monitors
   3. the patient's response to pre-medication
   4. all equipment and drugs for induction

47. To avoid being held for abandonment in the post-anesthesia recovery unit, the anesthesia provider should:
   1. document the name of the person caring for the patient
   2. document name and credentials as well as know the person's experience who is assuming the care of the patient
   3. no need to document anything just give a verbal report
   4. do not discharge the person to any other provider

48. The Harvard Standards for monitoring patients under anesthesia:
   1. encourage high quality patient care
   2. guarantee specific patient outcome
   3. will never change
   4. are maximum standards
49. Cardinal rules of documentation include:
   1. legible handwriting, subjective terms, and consistency
   2. legible handwriting, subjective terms, and approved abbreviations
   3. legible handwriting, hospital-approved abbreviations, signature, date and time of entries
   4. legible handwriting, white out, signature, date and time of entries

50. Stress and anxiety may diminish patient recall of the anesthesia pre-operative visit. In order to protect the anesthesia provider, the following documentation is advisable:
   1. written anesthesia consent statement with no signatures
   2. written anesthesia consent statement with the patient’s signature alone
   3. written anesthesia consent statement with provider’s signature alone
   4. written anesthesia consent statement with both provider and patient’s signatures

51. General controls require manufacturers to perform all the following, except:
   1. register and list with the FDA
   2. bench, animal and clinical studies
   3. conform to good manufacturing practices provisions
   4. notify health care providers of health risks associated with violative, misbranded or adulterated products

52. The least stringent requirements of pre-market approval of medical devices are:
   1. pre-market approval
   2. performance standards
   3. general controls
   4. voluntary standards

53. Class III is intended for all devices that are:
   1. substantially equivalent to other devices
   2. life-supporting, life-sustaining
   3. exported
   4. low risk when used as intended

54. Who are required to report to the FDA under the Mandatory Medical Device Reporting Regulation:
   1. health care professionals
   2. distributors
   3. hospitals
   4. manufacturers and importers

55. The majority of reports received in the MDR database are:
   1. deaths
   2. injuries
   3. disconnections
   4. malfunctions

56. The pre-use check list for anesthesia gas machines is designed to detect all of the following except:
   1. vaporizer miscalibration
   2. low pressure leaks
   3. misconnections
   4. fail-safe systems

57. Which of the following devices requires premarket approval:
   1. anesthesia gas machine
   2. lung water monitor
   3. esophageal stethoscope
   4. autotransfusion apparatus

58. The overall risks of a violative product are evaluated during:
   1. premarket notification
   2. a recall
   3. Health Hazard Committee meeting
   4. premarket approval

59. The FDA may learn of a patient injury or device malfunction through all the following except:
   1. Mandatory Device Reporting Program
   2. Problem Reporting Program
   3. United States Pharmacopeia
   4. Arthur D. Little Co.

60. The anesthesia gas machine would be best categorized as medical device classification:
   1. Class I
   2. Class II
   3. Class III
   4. none of the above
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Without any other agent or premedicant, isoflurane provides every action required for a complete anesthetic, on a closely controlled, breath-by-breath basis: unconsciousness, surgical analgesia, amnesia, and good surgical muscle relaxation—a useful advantage for laparoscopies and orthopedic work, and one that begins when the anesthetic begins and ends with elimination of the anesthetic, thereby decreasing the risk of residual paralysis in the PAR.

Because isoflurane is a complete anesthetic when given alone in oxygen or room air, nitrous oxide can be eliminated if you choose. Isoflurane anesthetics are seldom complicated and prolonged by postoperative nausea and vomiting.
Excellent Safety Profile

Stability of heart rhythm and good cardiac output are notable features of an isoflurane anesthetic. CNS excitation does not occur at any concentration or PaCO$_2$ level. Virtually 100% of isoflurane is exhaled unchanged from the patient (only 0.17% of the isoflurane taken up is recovered as metabolites). This near absence of metabolic by-products all but assures an absence of hepatic or renal toxicity from metabolism.
For outpatient anesthesia

FORANE®
(isoflurane, USP)

Rapid...Complete...Excellent Safety Profile

CAUTION Federal Law Prohibits Dispensing without Prescription

DESCRIPTION
FORANE isoflurane USP is a stimulable liquid administered by vaporizing a general anesthetic. It is a 1:1:1.2 (isoflurane:dimethyl ether:chlorofluorocarbon) mixture, and its structural formula is:

\[
\text{F - CON} - C - C \rightarrow \text{H}
\]

Some physical constants are:

- Molecular weight: 184.4
- Boiling point: 760 mm Hg
- Refractive index: 1.4966
- Specific gravity: 0.546
- Vapor pressure at 25°C: 0.55 mm Hg
- Vapor pressure at 37°C: 1.0 mm Hg
- Vapor pressure at 40°C: 1.5 mm Hg
- Vapor pressure at 45°C: 2.0 mm Hg

\[\text{Equation for vapor pressure calculation:}\]

\[p = \frac{A}{T} + \frac{B}{T^2}\]

\[p = \frac{A}{T} + \frac{B}{T^2}\]

\[A = 0.015\text{ atm}\]

\[B = 0.000450\text{ atm} \cdot \text{°C}^{-1}\]

\[p = \frac{A}{T} + \frac{B}{T^2}\]

Partition coefficients:

- Water/gas: 0.86
- Blood/gas: 1.43
- Tissue/gas: 9.08
- Muscle/gas: 99.9

Increased blood loss compatible to that seen with halothane has been observed in patients undergoing surgery.

FORANE (isoflurane) increases cerebral blood flow at all levels of anesthesia. There may be a transient rise in cerebral blood flow pressure which is fully reversible with hyperventilation.

PRECAUTIONS
General: As with any potent general anesthetic, FORANE (isoflurane) USP should only be administered in an adequately equipped anesthetic environment by those who are familiar with the pharmacology of the drug and qualified by training and experience to manage the anesthetized patient.

Information in Patients—FORANE isoflurane USP is contraindicated in patients with known or suspected genetic susceptibility to malignant hyperthermia. As with other general anesthetics, small changes in skeletal muscle tone and movements may occur during administration and should be monitored. These changes should be returned to baseline before any muscle relaxant is administered. In the event of a drug-induced malignant hyperthermia, the attending anesthesiologist should as soon as practical administer dantrolene sodium, an inhibitor of sarcoplasmic reticulum calcium pump, to the patient. Neutron therapy and supportive measures should be provided to the patient. Supportive therapy such as vigorous efforts to restore body temperature, normal and respiratory support, and fluid administration should be provided. If the patient has been determined to be at risk for malignant hyperthermia, administration of intravenous dantrolene sodium should be initiated to prevent a potentially lethal event.

FOLLOWING ADMINISTRATION
FORANE (isoflurane) USP may be administered to a nursing woman. See CLINICAL PHARMACOLOGY for information regarding malignant hyperthermia.

OVERDOSE
In the event of overdose or lack of anesthesia, the following actions should be taken:

- Stop drug administration: establish a clear airway and institute assisted or controlled ventilation with pure oxygen.

- DOSAGE AND ADMINISTRATION

- Indications: FORANE USP is used as a maintenance anesthetic. The MAC minimal alveolar concentrations in man is as follows:

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>0-10</th>
<th>10-20</th>
<th>20-50</th>
<th>50-60</th>
<th>60+</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAC (%)</td>
<td>1.7</td>
<td>1.3</td>
<td>1.1</td>
<td>1.0</td>
<td>0.8</td>
</tr>
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</table>

- Adverse reactions encountered in the administration of FORANE (isoflurane) USP are as follows:

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased blood pressure or pulse rate</td>
<td>1-5%</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>1-5%</td>
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<tr>
<td>Hypotension</td>
<td>1-5%</td>
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<tr>
<td>Bradycardia</td>
<td>1-5%</td>
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<tr>
<td>Bronchospasm</td>
<td>1-5%</td>
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<tr>
<td>Hypothermia</td>
<td>1-5%</td>
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<tr>
<td>Cyanosis</td>
<td>1-5%</td>
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<tr>
<td>Apnea</td>
<td>1-5%</td>
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- DOSAGE AND ADMINISTRATION

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<tr>
<td>Cyanosis</td>
<td>1-5%</td>
</tr>
<tr>
<td>Apnea</td>
<td>1-5%</td>
</tr>
</tbody>
</table>

- DOSAGE AND ADMINISTRATION

- Indications: FORANE USP is used as a maintenance anesthetic. The MAC minimal alveolar concentrations in man is as follows:

<table>
<thead>
<tr>
<th>Age (Years)</th>
<th>0-10</th>
<th>10-20</th>
<th>20-50</th>
<th>50-60</th>
<th>60+</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAC (%)</td>
<td>1.7</td>
<td>1.3</td>
<td>1.1</td>
<td>1.0</td>
<td>0.8</td>
</tr>
</tbody>
</table>

- Adverse reactions encountered in the administration of FORANE (isoflurane) USP are as follows:

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased blood pressure or pulse rate</td>
<td>1-5%</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>1-5%</td>
</tr>
<tr>
<td>Hypotension</td>
<td>1-5%</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>1-5%</td>
</tr>
<tr>
<td>Bronchospasm</td>
<td>1-5%</td>
</tr>
<tr>
<td>Hypothermia</td>
<td>1-5%</td>
</tr>
<tr>
<td>Cyanosis</td>
<td>1-5%</td>
</tr>
<tr>
<td>Apnea</td>
<td>1-5%</td>
</tr>
</tbody>
</table>
In **Reversal** of nondepolarizing muscle relaxants, don’t look for what’s better... ...look for what’s best

**Regonol®**

*(pyridostigmine bromide injection, USP)*

when compared to neostigmine

- Clinically fewer side effects
- Significantly lower degree and incidence of:
  1) Bradycardia
  2) Salivation
  3) Gastrointestinal stimulation
- Wide margin of safety\(^{1,2}\)

Organon Pharmaceuticals
A Division of Organon Inc.
West Orange, N.J. 07052

OR-5091
REGONOL (pyridostigmine bromide) for i.v. use

BRIEF SUMMARY—(Please consult full package insert enclosed in every package, before using REGONOL)

INDICATIONS—Pyridostigmine bromide is useful as a reversal agent or antagonist to nondepolarizing muscle relaxants.

CONTRAINdications—Known hypersensitivity to anticholinesterase agents, intentional and suicidal destructions of mechanichal type.

WARNINGS—Pyridostigmine bromide should be used with particular caution in patients with bronchial asthma or cardiac dysrhythmias. Transient bradycardia may occur and be relieved by atropine sulfate. Atropine should also be used with caution in patients with cardiac dysrhythmias. When large doses of pyridostigmine bromide are administered, as during reversal of muscle relaxants, prior or simultaneous injection of atropine sulfate is advisable. Because of the possibility of hypersensitivity in an occasional patient, atropine and antishock medication should always be readily available.

When used as an antagonist to nondepolarizing muscle relaxants, adequate recovery of voluntary respiration and neuromuscular transmission must be obtained prior to discontinuation of respiratory assistance and there should be continuous patient observation. Satisfactory recovery may be defined by a combination of clinical judgement, respiratory measurements and observation of the effects of peripheral nerve stimulation: If there is any doubt concerning the adequacy of recovery from the effects of the nondepolarizing muscle relaxant, artificial ventilation should be continued until all doubt has been removed.

Use in Pregnancy—The safety of pyridostigmine bromide during pregnancy or lactation in humans has not been established. Therefore its use in women who are pregnant requires weighing the drug's potential benefit against its possible hazards to mother and child.

ADVERSE REACTIONS—The side effects of pyridostigmine bromide are most commonly related to overdosage and generally are of two varieties, muscarinic and nicotinic. Among those in the former group are nausea, vomiting, diarrhea, abdominal cramps, increased peristalsis, increased salivation, increased bronchial secretions, miosis and diaphoresis. Muscarinic side effects are comprised chiefly of muscle cramps, fasciculation and weakness. Muscarinic side effects are comprised chiefly of muscle cramps, fasciculation and weakness. Nicotinic side effects are comprised chiefly of muscle cramps, fasciculation and weakness. Muscarinic side effects are comprised chiefly of muscle cramps, fasciculation and weakness. Nicotinic side effects are comprised chiefly of muscle cramps, fasciculation and weakness.

DOSEAGE AND ADMINISTRATION—When pyridostigmine bromide is given intravenously to reverse the action of muscle relaxant drugs, it is recommended that atropine sulfate (0.5 to 1.2 mg) or glycopyrrolate in equipotent doses be given intravenously immediately prior to or simultaneously with its administration. Side effects, notably excessive secretions and bradycardia, are thereby minimized. Reversal doses range from 0.5 to 2.5 mg. Usually 10 to 20 mg of pyridostigmine bromide will be sufficient for antagonism of the effects of the nondepolarizing muscle relaxant. Although full recovery may occur within 15 minutes in most patients, others may require a half hour or more. Satisfactory reversal can be evidenced by adequate voluntary respiration, respiratory measurements and use of a peripheral nerve stimulation device. It is recommended that the patient be well ventilated and a patent airway maintained until complete recovery of normal respiration is assured. Once satisfactory reversal has been attained, reanimation has not been reported.

Failure of pyridostigmine bromide to provide prompt (within 30 minutes) reversal may occur, e.g., in the presence of extreme dehydration, cataractogenesis, or with excessive use of certain broad spectrum antibiotics or anesthetic agents, notably ether. Under these circumstances, ventilation must be supported by artificial means until the patient has resumed control of his respiration.

HOW SUPPLIED—Regonol is available in 5 mg/ml 2 ml ampuls—boxes of 25—NDC 0052-0460-02

5 ml vials—boxes of 25—NDC 0052-0460-05

REFERENCES:


Dunhill Means Medical Specialists

At Dunhill of Charlotte we have specialized in the placement of CRNAs for over 25 years. If you are searching for a new career challenge and opportunity, we would like to talk with you today!

We specialize in the placement of CRNAs. Our medical specialists can connect you with outstanding opportunities on all levels in the healthcare fields across the United States. We have a network of over 300 affiliated offices coast to coast, therefore you'll find no restrictions as to the locations you choose to explore.

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(704) 542-0312

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CRNA
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We have an immediate opening for a CRNA with ARNP license in Florida. You must have surgery and OB anesthesia experience and be current in all techniques. This is a full time position and may have some shift rotation and flexible hours if necessary.

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Broward General Medical Center, 1600 S. Andrews Avenue, Ft. Lauderdale, FL 33316. An Equal Opportunity Employer.
One agent has inspired a new way of looking at surgical muscle relaxation.
**TRACRIUM® INJECTION**
*(atracurium besylate)*

**Intrinsically predictable, uncommonly flexible**

- **Predictable because it doesn't accumulate.**
  
  Equal maintenance doses of Tracrium, repeated at equal time intervals during surgery, have no cumulative effect on recovery time. Once recovery begins following the last administered dose, it is relatively rapid and independent of the total dose. Thus, you need not calculate progressively smaller doses of Tracrium for repeat administration. Recovery is more consistent and predictable.

- **Metabolized independent of liver or kidney function.**

  Tracrium Injection (atracurium besylate) is not dependent on kidney or liver function for elimination. It is inactivated by two nonoxidative pathways:
● Few cardiovascular effects.
At recommended doses, Tracrium produces virtually no clinically significant cardiovascular hemodynamic effects—an advantage over tubocurarine, metocurine, and pancuronium in patients with compromised cardiac ability or cardiac risk.

● Minimal histamine release at recommended doses.
Tracrium Injection is a less potent histamine releaser than d-tubocurarine or metocurine.
Clinically significant changes (about 200% of control) in arterial pressure and heart rate resulting from histamine release occur well within the clinical dosage range (at ED₉₅) for curare, at the upper limits of the clinical dosage range (at 2 x ED₉₅) for metocurine, and outside the clinical dosage range (at 3 x ED₉₅) for atracurium.¹

● No mixing. Ready to use.
Good stability.
Tracrium is easily administered, requiring no premixing or measuring. At room temperature (25°C), potency loss is 5% per month.

Multiple-dose vials can reduce the amount of Tracrium subject to waste by as much as 22% when compared to ampules!*  
*(Data on file, Burroughs Wellcome Co.)

Gives you superior control and predictability

TRACRIUM® INJECTION
(atracurium besylate)

Reference:

*Please see brief summary of prescribing information on following page.

Burroughs Wellcome Co.
Research Triangle Park
North Carolina 27709
TRACRIUM® INJECTION
(atracurium besylate)

Brief Summary
This drug should be used only by adequately trained individuals familiar with its actions, characteristics, and hazards.

CONTRAINdications: Tracrium is contraindicated in patients known to have a hypersensitivity to it.

WARNINGS: TRACRIUM SHOULD BE USED ONLY BY THOSE SKILLED IN AIRWAY MANAGEMENT AND RESPIRATORY SUPPORT EQUIPMENT AND PERSONNEL. MUSCLE RELAXANTS SHOULD NOT BE USED TO SELECT OR SUPPORT VENTILATION, INCLUDING ADMINISTRATION OF POSITIVE PRESSURE OXYGEN. ADEQUACY OF RESPIRATION MUST BE ASSURED THROUGH ASSISTED OR CONTROLLED VENTILATION. ANTIChOLINESTERASE REVERSAL OF NEUROMUSCULAR BLOCKADE SHOULD NOT BE ATTEMPTED.

DO NOT GIVE TRACRIUM BY INTRAMUSCULAR ADMINISTRATION.

Tracrium has no known effect on consciousness, pain threshold, or cerebration. It should be used only with adequate anesthesia.

Tracrium injection, which has an acid pH, should not be mixed with alkaline solutions (e.g., barbiturate solutions) in the same syringe or administered simultaneously during intravenous infusion through the same needle. Depending on the resultant pH of such mixtures, Tracrium may be inactivated and a free acid may be precipitated.

PRECAUTIONS:
General: Although Tracrium is a less potent histamine releaser than d-tubocurarine or metocurine, the possibility of substantial histamine release in sensitive individuals must be considered. Special caution should be exercised in administering Tracrium to patients in whom substantial histamine release would be especially hazardous (e.g., patients with clinically significant cardiovascular disease) and in patients with any history (e.g., severe anaphylactoid reactions or asthma) suggesting a greater risk of histamine release. In these patients, the recommended initial Tracrium dose is lower (0.3 to 0.4 mg/kg) than for other patients and should be administered slowly or in divided doses over one minute.

Since Tracrium has no clinically significant effects on heart rate in the recommended dosage range, it will not counteract the bradycardia produced by many anesthetic agents or vagal stimulation. As a result, bradycardia during anesthesia may be more common with Tracrium than with other muscle relaxants.

Tracrium may have profound effects in patients with myocardia gravis, Eaton-Lambert syndrome, or other neuromuscular diseases in which potentiation of nonpolarizing agents has been noted. The use of a peripheral nerve stimulator is especially important for assessing neuromuscular blockade in these patients. Similar precautions should be taken in patients with severe electrolyte disorders or carciromatosis.

The safety of Tracrium has not been established in patients with bronchial asthma.

Drug Interactions: Drugs which may enhance neuromuscular blocking action of Tracrium include: enflurane; isofluorane; halothane; certain antibiotics, especially the aminoglycosides and polymyxins; lithium; magnesium salts; procaineamide; and quindeine.

If other muscle relaxants are used during the same procedure, the possibility of a synergistic or antagonistic effect should be considered.

Pregnancy: Teratogenic Effects: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. Tracrium should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Labor and Delivery: It is not known whether muscle relaxants administered during vaginal delivery have immediate or delayed adverse effects on the fetus or increase the likelihood that resuscitation of the newborn will be necessary. The possibility that forces delivered will be necessary may increase.

Tracrium (0.3 mg/kg) has been administered to 25 pregnant women during delivery by cesarean section. No harmful effects were attributable to Tracrium in any of the newborn infants. Although small amounts of Tracrium were shown to cross the placental barrier, the possibility of respiratory depression in the newborn infant should always be considered following cesarian section during which a neuromuscular blocking agent has been administered. In patients receiving magnesium sulfate, the reversal of neuromuscular blockade may be unsatisfactory and Tracrium dose should be lowered as indicated.

Nursing Mothers: It is not known whether the drug is excreted in human milk.

Pediatric Use: Safety and effectiveness in children below the age of 1 month have not been established.

ADVERSE REACTIONS:
Observed: In Controlled Clinical Studies: Tracrium produced few adverse reactions during extensive clinical trials. Most were suggestive of histamine release (see Precautions Section). The overall incidence rate for clinically important adverse reactions was 7/85 or 0.8%.

Most adverse reactions were of little clinical significance unless they were associated with significant hemodynamic changes. Substantial vital sign changes greater than 30% observed in 535 patients, without cardiovascular disease, were as follows: in those patients given the recommended initial dosage range of 0.3 to 0.5 mg/kg of Tracrium, mean arterial pressure increased in 2.9% and decreased in 2.1% of patients while the heart rate increased in 2.9% of these patients with 0% change in heart rate. At doses of 0.6 mg/kg, 14.3% of the studied patients had a decrease in mean arterial pressure while 4.8% had an increase in heart rate.

Observed in Clinical Practice: Based on clinical experience in the U.S. and the United Kingdom of approximately 3 million patients given Tracrium the following adverse reactions are among the most frequent reported: General: allergic reactions (anaphylactic or anaphylactoid) which, in rare instances, were severe (e.g., cardiac arrest), Musculoskeletal: inadequate, Cardiovacular: hypotension, tachycardia, bradycadria; Respiratory: dyspnea, bronchospasam, laryngospasm; Integumentary: rash, urticaria, injection site reaction.

DOSAGE AND ADMINISTRATION: Tracrium should be administered intravenously. DO NOT GIVE TRACRIUM BY INTRAMUSCULAR ADMINISTRATION.

Bolus Doses for Intubation and Maintenance of Neuromuscular Blockade:
Adults: A Tracrium dose of 0.4 to 0.5 mg/kg, given as an intravenous bolus injection, is the recommended initial dose for most patients. With this dose, good or excellent conditions for nonemergent intubation can be expected in 2 to 5 minutes in most patients, with maximum neuromuscular blockade achieved approximately 3 to 5 minutes after injection. Clinically required neuromuscular blockade generally lasts 20 to 35 minutes under balanced anesthesia. Under balanced anesthesia, recovery to 25% of control is achieved approximately 35 to 45 minutes after injection, and recovery is usually 95% complete approximately 60 minutes after injection.

Tracrium is potentiated by isoflurane or enfurane anesthesia. The same initial Tracrium dose of 0.4 to 0.5 mg/kg may be used for intubation prior to administration of these inhalation agents; however, if Tracrium is first administered under steady state of isoflurane or enfurane, the initial Tracrium dose should be reduced by approximately one-third, i.e., to 0.25 to 0.35 mg/kg, to adjust for the potentializing effects of these anesthetic agents. With halothane, which has only a marginal (approximately 20%) potentiating effect on Tracrium, smaller dosage reductions may be required.

Tracrium doses of 0.08 to 0.10 mg/kg are recommended for maintenance of neuromuscular blockade during prolonged surgical procedures. The first maintenance dose will generally be required 20 to 45 minutes after the initial Tracrium injection, but the need for maintenance doses should be determined by clinical criteria.

Children and Infants: No Tracrium dosage adjustments are required for pediatric patients two years of age or older. A Tracrium dose of 0.3 to 0.4 mg/kg is recommended as the initial dose for infants (1 month to 2 years of age) under halothane anesthesia. Maintenance doses may be required with slightly greater frequency in infants and children than in adults.

Special Considerations: An initial Tracrium dose of 0.3 to 0.4 mg/kg, given slowly or in divided doses over one minute, is recommended for adults, children, or infants with significant cardiovascular disease and for adults, children, or infants with any history (e.g., severe anaphylactoid reactions or asthma) suggesting a greater risk of histamine release.

Doseage reductions must be considered also in patients with neuromuscular disease, severe electrolyte disorders, or carciromatosis in which potentiation of neuromuscular blockade or difficulties with reversal have been demonstrated. There has been no clinical experience with Tracrium in these patients, and no specific dosage adjustments can be recommended.

No Tracrium dosage adjustments are required for patients with renal disease.

Use by Infusion: After administration of a recommended initial bolus dose of Tracrium (0.3 to 0.5 mg/kg), a diluted solution of Tracrium can be administered by continuous infusion to adults and children aged 2 or more years for maintenance of neuromuscular blockade during extended surgical procedures. Infusion of Tracrium should be individualized for each patient. The rate of administration should be adjusted according to the patient's response as determined by peripheral nerve stimulation.

Infusion of Tracrium should be initiated only after early evidence of spontaneous recovery from the bolus dose. An initial infusion rate of 9 to 10 μg/kg/min may be required to rapidly counteract the spontaneous recovery of neuromuscular function. Thereafter, a rate of 5 to 9 μg/kg/min should be adequate to maintain continuous neuromuscular blockade in the range of 89 to 99% in most pediatric and adult patients under balanced anesthesia.

The neuromuscular blocking effect of Tracrium administered by infusion is potentiated by enflurane or isoflurane and, to a lesser extent, by halothane. Reduction in the infusion rate of Tracrium should, therefore, be considered for patients receiving inhalation anesthesia. The rate of Tracrium infusion should be reduced by approximately one-third in the presence of steady-state enflurane or isoflurane anesthesia; smaller reductions should be considered in the presence of halothane. In patients undergoing cardiopulmonary bypass with induced hypothermia, the rate of infusion of Tracrium required to maintain adequate surgical relaxation during hypothermia (23° to 28°C) has been shown to be approximately half the rate required during normothermia.

Spontaneous recovery from neuromuscular blockade following discontinuation of Tracrium infusion may be expected to proceed at a rate comparable to that following administration of a single bolus dose.

Tracrium infusion solutions may be prepared by admixing Tracrium injection with an appropriate diluent such as 5% Dextrose Injection USP, 0.9% Sodium Chloride Injection USP, or 5% Dextrose and 0.9% Sodium Chloride Injection USP. Infusion solutions should be used within 24 hours of preparation. Spontaneous degradation of Tracrium has been demonstrated to occur more rapidly in lactated Ringer’s solution than in 0.9% sodium chloride solution. Therefore, it is recommended that Lactated Ringer’s Injection USP not be used as a diluent in preparing solutions of Tracrium for infusion.

The amount of infusion solution required per minute will depend upon the concentration of Tracrium in the infusion solution and the dose of Tracrium desired (see table).

<table>
<thead>
<tr>
<th>Drug Delivery Rate (μg/kg/min)</th>
<th>Infusion Delivery Rate (mL/kg/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.2 mg**</td>
<td>0.025</td>
</tr>
<tr>
<td>0.3 mg**</td>
<td>0.035</td>
</tr>
<tr>
<td>0.4 mg**</td>
<td>0.045</td>
</tr>
<tr>
<td>0.5 mg**</td>
<td>0.050</td>
</tr>
</tbody>
</table>

**2 ml of 1% (10 mg/ml) Tracrium injection added to 98 ml of diluent
*5 ml of 1% (10 mg/ml) Tracrium injection added to 95 ml of diluent

U.S. Patent No. 4179507

TRACRIUM® INJECTION
(atracurium besylate)

85TRA16

Burroughs Wellcome Co.
Research Triangle Park
North Carolina 27709
The logical premedicant for 6 to 8 hour procedures

Duration of action designed for lengthy surgery
- cardiac surgery
- major vascular flaps
- organ transplantation
- colon surgery
- Whipple's procedure
- Harrington rods
- limb or digit reimplantation
- spinal fusions

Excellent benefit/risk profile
Sedation: leaves patient arousable and cooperative before induction
Anxiolytic effect: relieves preoperative anxiety
Reliable amnesia: reduces recall for preoperative events

The ease and economy of a single injection
Repeat administration rarely needed

Little if any IV irritation at proper dilution. Minimal effect on blood pressure, pulse or respiratory rate. Compatible with narcotic analgesics.

Please see important information on the adjacent page.
DESCRIPTION: Ativan (lorazepam) Injection, a benzodiazepine, is supplied as a clear, colorless solution of lorazepam, USP, 0.18 mg polyethylene glycol 400 in propylene glycol with 0.2% benzyl alcohol as preservative.

CLINICAL PHARMACOLOGY:

The recommended adult dosage of lorazepam injection is 0.1 mg IV or IM, followed by appropriate adjustments of dosage. Lorazepam may be given IV as a bolus injection or may be administered by continuous intravenous infusion (see DRUG INTERACTIONS). In the elderly, the minimum effective dose of lorazepam injection is usually 0.5 to 1.0 mg intramuscularly or intravenously. In patients with hepatic or renal disease, the minimum effective dose of lorazepam injection is usually 0.25 to 1.0 mg intramuscularly or intravenously.

When given intravenously, lorazepam injection may be diluted in 5% dextrose injection, USP, or sterile water for injection, USP, and administered at a rate not exceeding 20 mg per minute. Lorazepam injection is compatible for dilution purposes with: Sterile Water for Injection, USP, Sodium Chloride Injection, USP, 5% Dextrose Injection, USP, TUBEX* Sterile Cartridge-Needle Units, Magnesium Sulphate Injection, USP, and Mannitol Injection, USP. The solution is discolored or contains a precipitate. In such cases, the solution should not be used.

Overdosage: If an acute toxicity occurs, supportive and symptomatic therapy should be given. There is no known specific antidote for the treatment of lorazepam overdose. Hemodialysis is not likely to be of significant benefit due to the low degree of protein binding of lorazepam in plasma.

SIDE EFFECTS: The most frequent adverse effects of lorazepam injection are drowsiness, sedation, and dizziness. Of the 1500 patients treated in clinical studies, approximately 40% noted drowsiness. Other adverse effects included somnolence, drowsiness, sedation, and dizziness. In clinical studies, the incidence of drowsiness and dizziness was highest in patients over 65 years of age.

INSTRUCTIONS: IM/LD: 0.05 mg/kg. IV/LD: 0.03 to 0.05 mg/kg. If patients are to be given more than one injection, the second injection should be given at least 2 to 4 hours after the previous one.

DRUG INTERACTIONS: Because of the ataxic nature of many of the benzodiazepines, it may be preferable to use lorazepam injection as the sole anxiolytic in patients with unstable cardiovascular disease. A benzodiazepine should be used cautiously in patients with unstable cardiovascular disease.

ADVERSE REACTIONS: Adverse reactions include ataxia, dizziness, drowsiness, and sedation. Drowsiness was a frequent complaint. The frequency of reported side effects was increased in patients with hepatic or renal disease. The administration of lorazepam injection to patients with hepatic or renal disease may produce more prolonged and profound effects. In patients with hepatic or renal disease, the adverse reactions may be more pronounced.

OVERDOSAGE: In case of an overdose, supportive and symptomatic therapy should be given. There is no known specific antidote for the treatment of lorazepam overdose. Hemodialysis is not likely to be of significant benefit due to the low degree of protein binding of lorazepam in plasma.

PREGNANCY: Category B. See CLINICAL PHARMACOLOGY. Warnings and Precautions: Use in Pregnancy: Because of its potential for fetal harm, lorazepam injection should not be used during pregnancy unless in clearly indicated circumstances. Nursing Mothers: Lorazepam is excreted in breast milk. A decision must be made whether to discontinue breast feeding or continue lorazepam injection in the mother.

LABORATORY TESTS: Routine laboratory tests and those tests which may be specific to a particular disease or condition should be performed according to the clinical needs of the patient. Lorazepam injection should not affect the results of the following tests: hematocrit, white blood cell count, thrombocyte count, or levels of serum bilirubin, alkaline phosphatase, or SGOT, SGPT, SGOT, or LDH.

NURSING MOTHERS: Lorazepam is excreted in breast milk. The decision to discontinue breast feeding or continue lorazepam injection in the mother must be made on the basis of the potential benefit to the patient. If the mother elects to breast feed, it is suggested that she be informed of the possible effects of lorazepam injection on the nursing infant.

LABORATORY TESTS: Routine laboratory tests and those tests which may be specific to a particular disease or condition should be performed according to the clinical needs of the patient. Lorazepam injection should not affect the results of the following tests: hematocrit, white blood cell count, thrombocyte count, or levels of serum bilirubin, alkaline phosphatase, or SGOT, SGPT, SGOT, or LDH.
See for yourself.

The only surgical muscle relaxant free of clinically significant cardiovascular and histamine-related side effects...

ideal for your patients, including those at risk.¹⁻⁵
See the safety for yourself.

Free of clinically significant cardiovascular effects.*

NORCURON® is the only surgical muscle relaxant for which no clinically significant cardiovascular effects were observed in clinical trials. In fact, even at 12 times effective doses, under halothane anesthesia, NORCURON® produced no tachycardia, hypotension, or abnormalities of cardiodynamic function.

Histamine release or histamine-related side effects unlikely to occur...even at 3.5 times the ED₉₅.⁵

NORCURON® has not been shown to significantly affect circulating histamine, mean arterial blood pressure, and heart rate even in doses at the upper extreme of the recommended clinical range.⁵

---

### The Effect of Nondepolarizing Muscle Relaxants*

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose (mg/kg)</th>
<th>xED₉₅</th>
<th>Histamine</th>
<th>Mean Arterial Pressure</th>
<th>Heart Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tubocurarine</td>
<td>0.5</td>
<td>1</td>
<td>410</td>
<td>78</td>
<td>115</td>
</tr>
<tr>
<td>Metocurine</td>
<td>0.5¹</td>
<td>2</td>
<td>212</td>
<td>79</td>
<td>119</td>
</tr>
<tr>
<td>Atracurium</td>
<td>0.6¹</td>
<td>3</td>
<td>192</td>
<td>80</td>
<td>108</td>
</tr>
<tr>
<td>Vecuronium</td>
<td>0.1</td>
<td>1.7</td>
<td>117</td>
<td>100</td>
<td>99</td>
</tr>
<tr>
<td>Vecuronium</td>
<td>0.2</td>
<td>3.5</td>
<td>87</td>
<td>99</td>
<td>102</td>
</tr>
</tbody>
</table>

* Adapted from Basta et al. ⁶
¹ 0.1 mg/kg higher than recommended dose.
Performance unaffected by renal function.\textsuperscript{6}

Despite administration of high doses of NORCURON\textsuperscript{6}, no significant differences in onset time, duration of action, or recovery index have been noted between patients with and without renal function.\textsuperscript{6}

| Comparative Indices of Neuromuscular Blockade for Patients With and Without Renal Function Given Equal Doses (0.14 mg/kg) of NORCURON\textsuperscript{6} (vecuronium bromide) by Bolus Injection\textsuperscript{1} |
|-----------------|-----------------|-----------------|
| Onset (min)     | 2.1 ± 0.6       | 1.8 ± 0.7       |
| Duration of time (min) to 90% recovery | 103.8 ± 12.9 | 104.1 ± 45.7 |
| Recovery index (min) | 20.7 ± 2.5     | 28.7 ± 22.7     |

\*Although high doses of NORCURON\textsuperscript{6} were used to assess its pharmacokinetics, it is recommended that the initial dose not exceed 0.06 to 0.1 mg/kg.

\textsuperscript{1}Adapted from Miller et al.\textsuperscript{5}

---

The surgical muscle relaxant ideal for virtually all patients including those at risk.

Norcuron\textsuperscript{\textregistered}
(vecuronium bromide) injection

See full prescribing information on following page.

**Drug Interactions:** Prior administration of succinylcholine may enhance the neuromuscular blocking effect of Norcuron®. In the case of succinylcholine-induced paralysis, the administration of Norcuron® should be delayed until the succinylcholine effect shows signs of waning off with succinylcholine as the residual agent. Initial doses of 0.04-0.06 mg/kg of Norcuron® may be administered to produce complete neuromuscular block within 5-15 minutes. Infants 2 months of age and older may take approximately 25-40 minutes. The use of Norcuron® before succinylcholine, is not infrequently encountered but has not been sufficiently studied.

Other nondepolarizing neuromuscular blocking agents (pancuronium, d-tubocurarine, metocurine, and gallamine) are used in the same manner as Norcuron®. This combination should be used with caution because of the increased risk of prolongation of the neuromuscular block.

**Inhalational Anesthetics:** Use of volatile inhalational anesthetics such as enflurane, isoflurane, and halothane with Norcuron® will enhance neuromuscular blockade. Potentiation is most prominent with use of enflurane and isoflurane. No clinically significant antagonism has been observed with halothane.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term studies in animals have not been performed to evaluate carcinogenic potential of or impairment of fertility. Category C. Animal reproduction studies have not been conducted with Norcuron®. It is also not known whether Norcuron® can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Norcuron® should be given to a pregnant woman only if clearly needed.

**Pediatric Use:** Infants under one year of age and older than 7 weeks are moderately more sensitive to Norcuron® on a mg/kg basis than adults and take about 1.5 times as long to recover. Information on infants is not available and does not permit recommendation on usage in neonates.

**ADVERSE REACTIONS:** Norcuron® was well tolerated and produced few adverse reactions during extensive clinical trials. Norcuron® is usually associated with some changes in blood pressure or heart rate. These changes are most evident in patients with myocardial disease. Because of the short duration of action, they are not likely to produce clinically significant hypotensive or hypertensive episodes. Cardiac arrhythmias are rare; however, they may be posture induced. In prolonged anaesthesia, electrocardiographic changes were not associated with a decrease in the dose of Norcuron®.

Several possible explanations for these effects have been advanced. These include the following: (1) the ability of the nervous system to release endogenous acetylcholine and other hormones in response to the stimulation of the central nervous system; (2) the ability of the peripheral nervous system to release endogenous acetylcholine and other hormones in response to the stimulation of the peripheral nervous system; and (3) the ability of the autonomic nervous system to release endogenous acetylcholine and other hormones in response to the stimulation of the autonomic nervous system.

**SPECIAL PRECAUTIONS:** The use of volatile inhalational anesthetics such as enflurane, isoflurane, and halothane with Norcuron® will enhance neuromuscular blockade. Potentiation is most prominent with use of enflurane and isoflurane. No clinically significant antagonism has been observed with halothane.

**Drug/Laboratory Test Interactions:** None known.

**COMPATIBILITY:** Norcuron® will enhance neuromuscular blockade. Potentiation is most prominent with use of enflurane and isoflurane. No clinically significant antagonism has been observed with halothane.

**STORAGE:** Norcuron® (vecuronium bromide) injection is a nondepolarizing neuromuscular blocking agent of the benzylisoquinoline class. Norcuron® is readily reversed with various anticholinesterase agents, e.g. pyridostigmine, neostigmine, or physostigmine. Norcuron® does not cause histamine release in most patients.

**DOSAGE AND ADMINISTRATION:** Norcuron® (vecuronium bromide) injection is for intravenous use only. This product should be administered by or under the supervision of a physician familiar with the use of nondepolarizing neuromuscular blocking agents. Norcuron® is available for intravenous use only. This product has no significant effect on arterial blood pressure or heart rate. It has no significant effect on the production of respiratory acidosis or alkalosis. Norcuron® has a functional assay in patients and animals which is the same as that described in preclinical studies. Norcuron® can be administered as a bolus injection at the end of a surgical procedure. Norcuron® is a potent neuromuscular blocking agent which has a duration of action of approximately 30 minutes.