Drägermedical
A Dräger and Siemens Company

FEB - 6 2008

K072412

510(k) Summary
acc. to 21 CFR 807.92

Submitter's Name and Address: Dräger Medical AG & Co. KG
Moislinger Allee 53-55
23542 Lübeck
Germany

Contact Person: Dr Karin Luebbers
Senior Manager Regulatory Affairs

Phone: + 49 (451) 882-5367
Fax: + 49 (451) 882-7-5367

Applicant's US Contact Person: Ms Kathy Anderson
Senior Director Regulatory Affairs

Phone: (215) 660-2078
Fax: (215) 721-5424

Date submission was prepared: July 31st, 2007

Device Name:

Common Name:	Intensive Care Ventilator
Classification Name:	Continuous Ventilator
Regulation Number:	21 CFR 868.5895
Class:	2

Legally Marketed Device Identification: EvitaXL with SmartCare Option (K051263)

Device Description:

The EvitaXL is a time-cycled microprocessor-controlled intensive care ventilator. The option SmartCare™ for the EvitaXL has been developed for assisting physicians and respiratory therapists with the standardization of the weaning process used in intensive care units. The system uses a computerbased representation of a protocol and focusses on the management of pressure support.

Scope of this submission is an extension of claims made in the promotional material, while the device itself remains unchanged except for minor modifications that led to non-filing decisions. The indications for use, the intended use and the instructions for use also remain unchanged.

Intended Use:

The SmartCare/PS system is designed to stabilize the patient's spontaneous breathing in a "comfortable zone" and to reduce inspiratory support. SmartCare can be used for intubated or tracheotomized patients. Patients with body weight between 15 and 35 kg (33.1 and 77.8 lbs) must be endotracheally intubated and ventilated with active humidification. The patients should be haemodynamically stable with adequate oxygenation and spontaneous breathing.

Predicate Device:

510(k) Number	Device Name	Manufacturer
K051263	EvitaXL	Dräger Medical AG & Co. KG

Substantial Equivalence:

The device and its labelling are identical to the predicate device. Substancial equivalence is claimed on that basis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2008

Dräger Medical AG & Co. KG
C/O Ms. Kathy Anderson
Senior Director, Regulatory Affairs
Draeger Medical Systems, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K072412
Trade/Device Name: EvitaXL with Option SmartCare
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: January 18, 2008
Received: January 23, 2008

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: EvitaXL with Option SmartCare

Indications For Use: The EvitaXL is a long-term ventilator for intensive care for adults, children, and infants with a body weight of at least 3 kg (6.6 lbs).

With SmartCare™/PS the EvitaXL is intended to stabilize the patient's spontaneous breathing in a "comfortable zone" and to reduce inspiratory support for adults and children with a body weight of at least 15 kg (33 lbs). The patients should be haemodynamically stable with adequate oxygenation and spontaneous breathing. SmartCare can be used for intubated or tracheotomized patients. Patients with body weight between 15 and 35 kg (33.1 and 77.8 lbs) must be endotracheally intubated and ventilated with active humidification.

SmartCare™/PS is contraindicated in case of severe COPD and severe neurologic disorder that affects the cerebral control mechanism of the spontaneous breathing pattern.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072412

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2008

Dräger Medical AG & Co. KG
C/O Ms. Kathy Anderson
Senior Director, Regulatory Affairs
Draeger Medical Systems, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K072412
Trade/Device Name: EvitaXL with Option SmartCare
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: January 18, 2008
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Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: EvitaXL with Option SmartCare

Indications For Use: The EvitaXL is a long-term ventilator for intensive care for adults, children, and infants with a body weight of at least 3 kg (6.6 lbs).

With SmartCare™/PS the EvitaXL is intended to stabilize the patient's spontaneous breathing in a "comfortable zone" and to reduce inspiratory support for adults and children with a body weight of at least 15 kg (33 lbs). The patients should be haemodynamically stable with adequate oxygenation and spontaneous breathing. SmartCare can be used for intubated or tracheotomized patients. Patients with body weight between 15 and 35 kg (33.1 and 77.8 lbs) must be endotracheally intubated and ventilated with active humidification.

SmartCare™/PS is contraindicated in case of severe COPD and severe neurologic disorder that affects the cerebral control mechanism of the spontaneous breathing pattern.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072412

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 02, 2008

DRAGER MEDICAL AG & CO. KGAA
C/O DRAGER MEDICAL , INC.
3135 QUARRY ROAD
TELFORD, PA 18969
ATTN: KATHY ANDERSON

510(k) Number: K072412
Product: OPTION SMARTCARE FOR EVITAXL,SMARTCAR E KIT CAPNO

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

November 06, 2007

DRAGER MEDICAL AG & CO. KGAA
C/O DRAGER MEDICAL , INC.
3135 QUARRY ROAD
TELFORD, PA 18969
ATTN: KATHY ANDERSON

510(k) Number: K072412
Device: OPTION SMARTCARE FOR EVITAXL,SMARTCAR E KIT CAPNO

Extended Until: 12-DEC-2007

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Drägermedical

A Dräger and Siemens Company

Dräger Medical AG & Co. KG, Moislinger Allee 53-55, D-23542 Luebeck

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard

Rockville, Maryland 20850

U.S.A.

Date
November 2, 2007
Our ref.
gp-K072412_AI
Phone
+49 451 882-2041
Fax
+49 451 882-4351
E-Mail
gustav.paulsen@draeger.com

Premarket Notification 510(k) K072412 – Option SmartCare/PS for EvitaXL ventilator
Request for an Extension of Time

Dear Madam, Dear Sir,

This letter is to request an extension of time concerning the FDA request for additional information dated October 15, 2007, received for Option SmartCare/PS for EvitaXL

In order to adequately address all aspects of the FDA request, Dräger Medical AG & Co. KG requests an extension of time until December 12, 2007.

If there are any additional questions concerning this submission, please contact either the undersigned at (+ 49) 451-882 5367, or the assigned US-correspondent Ms. Kathy Andersen, Sr. Director Regulatory Affairs, Dräger Medical Systems, Inc., at (215) 660-2078

Sincerely,

Hans-Gustav Paulsen
Manager Regulatory Affairs

Dr. Karin Lübbers
Senior Manager Regulatory Affairs

K34

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2007

Dräger Medical AG & Co. KG
C/O Kathy Anderson
Senior Director Regulatory Affairs
Drager Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K072412
Option SmartCare/PS for the EvitaXL ventilator
Dated: August 23, 2007
Received: August 27, 2007

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information:

(b)(4) Trade Secret Process

[redacted]

(b)(4) Trade Secret Process

[redacted]

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Charles M. Kerns at 240-276-3775. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

For

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Dräger Medical AG & Co. KG
C/O Kathy Anderson
Senior Director Regulatory Affairs
Drager Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

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You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

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Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-480 DAGID
D.O.
F/T:HFZ-480:CMK:TTP:10/12/07

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-480	Kenny	10/12/07						
HFZ-480	Patel	10/12/07						

U.S. GPO 1986-169-089

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

August 28, 2007

DRAGER MEDICAL AG & CO. KGAA
C/O DRAGER MEDICAL , INC.
3135 QUARRY ROAD
TELFORD, PA 18969
ATTN: KATHY ANDERSON

510(k) Number: K072412
Received: 27-AUG-2007
Product: OPTION SMARTCARE FOR EVITAXL,SMARTCARE KIT CAPNO PACKAGE, CO2 SENSOR

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

an/ DAGD

Drägermedical

A Dräger and Siemens Company

K072412

Dräger Medical AG & Co. KG, Moislinger Allee 53-55, 23542 Lübeck, Germany

Food and Drug Administration
Center for Devices and Radiological Health
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9200 Corporate Boulevard
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USA

Date
2007-08-23
Our ref.
mt-pq-ra
Phone
+49 (0) 451 882 2041
Fax
+49 (0) 451 882 4351
E mail
gustav.paulsen@draeger.com

Special 510(k) Premarket Notification Option SmartCare / PS for the EvitaXL

Dear Madam, Dear Sir,

This Special 510(k) Premarket Notification is to notify FDA of Dräger Medical AG & Co. KG's intent to market the Option SmartCare / PS for the EvitaXL intensive care ventilator with additional promotional material.

Please find enclosed two (2) paper copies of this Special 510(k) Premarket Notification.

If there is a need to discuss any aspect of this Premarket Notification, please contact either the undersigned at +49 (451) 882-5367, or the assigned United States agent Ms. Kathy Anderson, Dräger Medical System, Inc., at (215) 660-2078.

Sincerely,

Gustav Paulsen
Manager Regulatory Affairs

Dr. Karin Lübbers
Senior Manager Regulatory Affairs

Enclosure: Two paper copies submitted,
Attachment: CDRH Submission Cover Sheet, Medical Device User Fee Cover Sheet

Dräger Medical AG & Co. KG
Moislinger Allee 53-55
D - 23558 Lübeck
Postanschrift: 23542 Lübeck
Telefon +49-18 05-3 72 34 37
Telefax +49-4 51-8 82-37 79
E-mail: business-support@draeger.com
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Konto-Nr. 0146795 00
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IBAN: DE95 2304 0022 0014 6795 00
SWIFT-Code: COBA DE FF 230
Dresdner Bank AG, Lübeck
Konto-Nr. 371 077 400
BLZ 230 800 40
IBAN: DE28 2308 0040 0371 0774 00
SWIFT-code: DRES DE FF 230

Sparkasse zu Lübeck
Konto-Nr. 107 111 7
BLZ 230 501 01
IBAN: DE15 2305 0101 0001 0711 17
SWIFT-Code: HSHN DE H1 SPL

Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRA 4435 HL

Komplementär:
Dräger Medical Verwaltungs AG
Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 5035
Vorsitzender des Aufsichtsrates:
Dipl.-Kfm. Theo Dräger
Vorstand:
Dipl.-Ing. (BA) Stefan Dräger (Vors.)
Dipl.-Kfm. Roland Jaksch

Drägermedical

A Dräger and Siemens Company

K072412

Dräger Medical AG & Co. KG, Moislinger Allee 53-55, 23542 Lübeck, Germany

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850
USA

K-4

FDA CDRH DMC
AUG 2 7 2007
RECEIVED

Date
2007-08-23
Our ref.
mt-pq-ra
Phone
+49 (0) 451 882 2041
Fax
+49 (0) 451 882 4351
E mail
gustav.paulsen@draeger.com

Special 510(k) Premarket Notification Option SmartCare / PS for the EvitaXL

Dear Madam, Dear Sir,

This Special 510(k) Premarket Notification is to notify FDA of Dräger Medical AG & Co. KG's intent to market the Option SmartCare / PS for the EvitaXL intensive care ventilator with additional promotional material.

Please find enclosed two (2) paper copies of this Special 510(k) Premarket Notification.

If there is a need to discuss any aspect of this Premarket Notification, please contact either the undersigned at +49 (451) 882-5367, or the assigned United States agent Ms. Kathy Anderson, Dräger Medical System, Inc., at (215) 660-2078.

Sincerely,

Gustav Paulsen
Manager Regulatory Affairs

Dr. Karin Lübbers
Senior Manager Regulatory Affairs

Enclosure: Two paper copies submitted,
Attachment: CDRH Submission Cover Sheet, Medical Device User Fee Cover Sheet

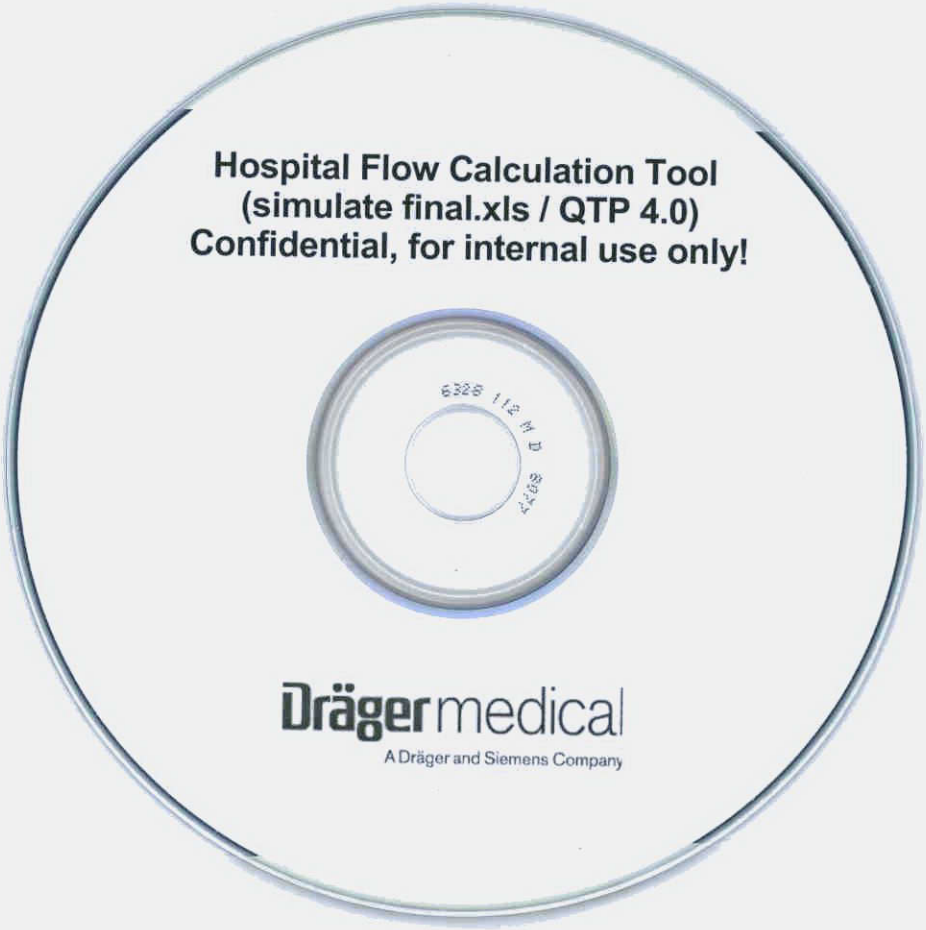
Hospital Flow Calculation Tool
(simulate final.xls / QTP 4.0)
Confidential, for internal use only!
Dräger medical
A Dräger and Siemens Company

Table of Contents for Special 510(k)

	6.7 CD Rom with Hospital Flow Calculation Tool Contents:simulate final.xls (Microsoft Excel Spread sheet) QTP 4.0 (neccessary Excel Plug in)
7	Performance and Testing Data - Clinical Validation 7.1 Lellouche F, Mancebo J, Jolliet P, Roeseler J, Schortgen F, Dojat M, et al. A multicenter randomized trial of computerdriven protocolized weaning from mechanical ventilation. AmJ Respir Crit Care Med 2006; 174:894-900. 7.2. Lewejohann, "Daily Practice With SmartCare ina Difficult to Wean Patient" in Respiratory Therapy: Vol 1 No. 3, May 2006 7.3 Dasta et al., "Daily cost of an intensive care unit day: The contribution of mechanical ventilation" in Crit Care Med: Vol 33 No.6, June 2005 7.4 "Increasing ICU Bed Capacity Decreases Ambulance Diversion and Increases Hospital Revenues", Internet Article by American College of Emergency Physicians, 2006 7.5 McManus et al., "Queuing Theory Accurately Models the Need for Critical Care Resources" in Anesthesiology: 100:1271–6, 2004 7.6 de Bruin, A.M., "Modelling and simulation for analysis of operative care chains" in European Journal of Anaesthesiology, Volume 21, Supplement 32, 2004 pg. 211, A-83 7.7 Institute for Healthcare Improvement, "Optimizing Patient Flow", Innovation Series 2003, IHI, Cambridge USA 7.8 Kraft et al., 'The savings potential of innovative medical technology in healthcare' Study by Medical Technology Department of the Technical University of Berlin, 2006
8	Financial Disclosure 8.1 Form FDA 3454 8.2 Attachment to Form 3454: CERTIFICATION 8.3 Form FDA 3455 8.4 Attachment to Form 3455: DISCLOSURE

Executive Summary

This special 510(k) Premarket Notification is to notify FDA of Dräger Medical AG & Co. KG's intent to market the option SmartCare / PS for the EvitaXL intensive care ventilator with additional promotional material.

The EvitaXL with SmartCare Option has not been changed in terms of technology or manufacturing since the 510(k) submission K#051263. Only minor modifications that led to non-filing decisions were performed.

SmartCare / PS has been developed for assisting physicians and respiratory therapists with the standardization of the weaning process used in intensive care units. The system uses a computer based representation of a clinical protocol for the management of pressure support (PS). The SmartCare system refers to measured patient data (respiratory rate, tidal volume, expiratory CO_2) and adjusts the pressure support provided by EvitaXL for the patients.

A recent clinical study that was conducted in seven major hospitals in Europe with over 1000 patients involved showed results, that are incorporated in the promotional material presented with this submission. The main results are:

- The weaning time can be reduced significantly,
- with this the total length of stay on the ICU can be reduced and
- ventilator induced complications can be reduced significantly.

Substantial equivalence is claimed to the predicate device EvitaXL by Dräger Medical AG & Co. KG (K051263).

This submission provides detailed information regarding the basis that the new promotional claims are based on. The revised promotional material is included.

If there is a need to discuss any aspect of this submission, please contact either

Dr. Karin Luebbers, Senior Manager Regulatory Affairs
Draeger Medical AG & Co. KG, Moislinger Allee 53-55, D-23542 Luebeck, Germany
Phone: 49 (451) 882-5367, Fax: 49 (451) 882-7-5367
Email: karin.luebbers@draeger.com

or

Ms Kathy Anderson, Senior Director Regulatory Affairs
Draeger Medical, Inc., 3135 Quarry Road, Telford, PA 18969

Phone (215)-660-2078, Fax: (215) 721-5424
Email: kathy.anderson@draegermed.com

CDRH SUBMISSION COVER SHEET

Date of Submission: May 10, 2007

FDA Document Number: Original Special 510(k)

Section A Type of Submission

PMA	PMA Supplement	PDP	510 (k)	Meeting
☐ Original Submission	☐ Regular	☐ Presubmission Summary	☒ Original Submission:	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Special	☐ Original PDP	☐ Traditional	☐ Pre-PMA Meeting
☐ Amendment	☐ Panel Track	☐ Notice of intent to start clinical trials	☒ Special	☐ Pre-PDP Meeting
☐ Report	☐ 30-Day Supplement	☐ Intention to submit Notice of Completion	☐ Abbreviated	☐ 180-Day Meeting
☐ Report Amendment	☐ 30-Day Notice	☐ Notice of Completion	☐ Additional Information:	☐ Other (specify):
	☐ 135-Day Supplement	☐ Amendment to PDP	☐ Traditional	
	☐ Real-time Review	☐ Report	☐ Special	
	☐ Amendment to PMA Supplement		☐ Abbreviated	

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original Submission	☐ Original submission	☐ Original submission	☐ Original submission	Describe submission:
☐ Amendment	☐ Amendment	☐ Additional information	☐ Additional information	
☐ Supplement	☐ Supplement			
	☐ Report			

Section B Applicant or Sponsor

Company / Institution name: Dräger Medical AG & Co. KG

Establishment registration number: 9611500

Division name (if applicable): N/A

Phone number (include area code): (011-49) 451-882-5367

Street address: Moislinger Allee 53 - 55

FAX number (include area code): (011-49) 451-882-4351

City: Luebeck

State / Province: N/A

Country: Germany

ZIP / Postal Code: D-23542

Contact name: Dr. Karin Luebbers

Contact title: Senior Manager, Regulatory Affairs

Contact e-mail address: karin.luebbers@draeger.com

Section C Submission correspondent (if different from above)

Company / Institution name: Draeger Medical Systems, Inc.

Establishment registration number: 2510954

Division name (if applicable): N/A

Phone number (include area code): (215) 660-2078

Street address: 3135 Quarry Rd.

FAX number (include area code): (215) 721-5424

City: Telford

State / Province: PA

Country: U.S.A.

ZIP / Postal Code: 18969

Contact name: Kathy Anderson

Contact title: Senior Director, Regulatory Affairs

Contact e-mail address: kathy.anderson@draegermed.com

	FDA Document Number: Original Traditional 510(k)

Section D1 — Reason for Submission – PMA, PDP, or HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)
- ☐ Response to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Other reason (specify):
- ☐ Change in design, component, or specification:
  - ☐ Software
- ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
- ☐ Other (Specify below)
- ☐ Labeling Change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
- ☐ Shelf life
- ☐ Trade Name
- ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
- ☐ Device defect
- ☐ Amendment
- ☐ Change in ownership
  - ☐ Change in correspondent

Section D2 — Reason for Submission – IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request
- ☐ Other reason (specify)
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ Protocol - feasibility
  - ☐ Protocol – other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting

Section D3 — Reason for Submission – 510 (k)

- ☐ New device
- ☐ Addition or expanded indications
- ☐ Other reason (specify):
- ☐ Change in technology
- ☐ Change in design
- ☐ Change in materials
- ☐ Change in manufacturing process

Change in Labelling

	FDA Document Number: Original Traditional 510(k)

Section E — Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data:
1 CBK	2	3	4	☒ 510(k) summary attached (see Section 16 of the submission)
5	6	7	8	☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K051263	1 Evita XL with Option SmartCare	1 Dräger Medical AG & Co. KG
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6
7	7	7

Section F — Product Information -- Applicable to All Applications

Common or usual name or classification name: Ventilator, continuous

Trade or proprietary or model name	Model number
1. Option SmartCare™ for EvitaXL	1. 84 15 941
2. SmartCare kit Capno package	2. 84 15 942
3. CO_2 sensor CapnoSmart	3. 68 71 500
4.	4.
5.	5.
6.	6.
7.	7.
8.	8.
9.	9.

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☐ Laboratory testing ☐ Animal trials ☒ Human trials

Section G — Product Classification – Applicable to All Applications

Product code: CBK	C.F.R. Section: 868.5895	Device class: ☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: Anesthesiology		

Indications (from labeling):
please see Section 4 of the 510(k) submission

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number: Original Traditional 510(k)

Section H Manufacturing/Packaging/Sterilization Sites Relating to a Submission

☒ Original ☐ Add ☐ Delete	FDA establishment registration number: 9611500	☒ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: Dräger Medical AG & Co. KG		Establishment registration number: 9611500	
Division name (if applicable): N/A		Phone number (include area code): 011 49 (451) 882-5367	
Street address: Moislinger Allee 53 – 55		FAX number (include area code): 011 49 (451) 882-4351	
City: Lübeck	State / Province: N/A	Country: Germany	City: Lübeck
Contact name: Dr. Karin Luebbers			
Contact title: Senior Manager Regulatory Affairs		Contact e-mail address: karin.luebbers@draeger.com	

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:		Contact e-mail address:	

☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code):	
Street address:		FAX number (include area code):	
City:	State / Province:	Country:	ZIP / Postal Code:
Contact name:			
Contact title:		Contact e-mail address:	

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Staten

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember tha the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no cas should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbc 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
DRAGER MEDICAL AG AND CO KGAA Moislinger Allee 53-55 Luebeck NO DATA 23542 DE	Dr. Karin Luebbers 2.1 E-MAIL ADDRESS karin.luebbers@draeger.com 2.2 TELEPHONE NUMBER (Include Area code) 49-451-882-5367
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) NO DATA	2.3 FACSIMILE (FAX) NUMBER (Include Area code) null-null

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:	3.1 Select one of the types below
[X] Premarket notification(510(k)); except for third party	[X] Original Application
[ ] Biologics License Application (BLA)	Supplement Types:
[ ] Premarket Approval Application (PMA)	[ ] Efficacy (BLA)
[ ] Modular PMA	[ ] Panel Track (PMA, PMR, PDP)
[ ] Product Development Protocol (PDP)	[ ] Real-Time (PMA, PMR, PDP)
[ ] Premarket Report (PMR)	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms

[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 31-Jul-2007

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

362

(b)(4) Trade Secret Process - Financial Data

Checklist for Traditional 510(k) Premarket Notification

acc. to ODE Screening Checklist for all Premarket Notification [510(k)] Submissions, Section 1 and 4

Contents	Provided in Section	Present or not applicable
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	0	☑
Table of Contents	1	☑
Truthful and Accurate Statement	2	☑
Device's Trade Name, Device's Classification Name and Establishment Registration Number	0	☑
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified)	0	☑
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual	6	☑
Statement of Indications for Use that is on a separate page in the premarket submission	4	☑
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual	5	☑
510(k) Summary or 510(k) Statement	3	☑
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals	5	☑
Identification of legally marketed predicate device	5	☑
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	na	☑
Class III Certification and Summary	na	na
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	8	☑
510(k) Kit Certification	na	na
Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation	na	na
Sterilization and expiration dating information: i) sterilization process ii) validation method of sterilization process iii) SAL iv) packaging v) specify pyrogen free vi) ETO residues vii) radiation dose viii) Traditional Method or Non-Traditional Method	na	na
Software Documentation	na	☑

Premarket Notification Truthful and Accurate Statement (Section 2)

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Md 20850

Premarket Notification
Truthful and Accurate Statement
(As required by 21 CFR 807.87(k))

I certify that, in my capacity as the Project Manager for the Option SmartCare / PS for EvitaXL, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Stefan Mersmann
Project Manager
Dräger Medical AG & Co. KG

2007/08/20
Date

Dräger medical
A Dräger and Siemens Company

510(k) Summary
acc. to 21 CFR 807.92

Submitter's Name and Address:
Dräger Medical AG & Co. KG
Moislinger Allee 53-55
23542 Lübeck
Germany

Contact Person:
Dr Karin Luebbers
Senior Manager Regulatory Affairs

Phone: + 49 (451) 882-5367
Fax: + 49 (451) 882-7-5367

Applicant's US Contact Person:
Ms Kathy Anderson
Senior Director Regulatory Affairs

Phone: (215) 660-2078
Fax: (215) 721-5424

Date submission was prepared: July 31st, 2007

Device Name:

Common Name:	Intensive Care Ventilator
Classification Name:	Continuous Ventilator
Regulation Number:	21 CFR 868.5895
Class:	2

Legally Marketed Device Identification: EvitaXL with SmartCare Option (K051263)

Device Description:

The EvitaXL is a time-cycled microprocessor-controlled intensive care ventilator. The option SmartCare™ for the EvitaXL has been developed for assisting physicians and respiratory therapists with the standardization of the weaning process used in intensive care units. The system uses a computerbased representation of a protocol and focusses on the management of pressure support.

Scope of this submission is an extension of claims made in the promotional material, while the device itself remains unchanged except for minor modifications that led to non-filing decisions. The indications for use, the intended use and the instructions for use also remain unchanged.

Intended Use:

The SmartCare/PS system is designed to stabilize the patient's spontaneous breathing in a "comfortable zone" and to reduce inspiratory support. SmartCare can be used for intubated or tracheotomized patients. Patients with body weight between 15 and 35 kg (33.1 and 77.8 lbs) must be endotracheally intubated and ventilated with active humidification. The patients should be haemodynamically stable with adequate oxygenation and spontaneous breathing.

Predicate Device:

510(k) Number	Device Name	Manufacturer
K051263	EvitaXL	Dräger Medical AG & Co. KG

Substantial Equivalence:

The device and its labelling are identical to the predicate device. Substancial equivalence is claimed on that basis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2005

Drager Medical AG & Co. KGAA
c/o Ms. Monica Ferrante
Director of Regulatory Affairs
Drager Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K051263
Trade/Device Name: EvitaXL with Option SmartCare
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: April 29, 2005
Received: May 16, 2005

Dear Ms. Ferrante:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 051263

Device Name: EvitaXL with Option SmartCare

Indications For Use: The EvitaXL is a long-term ventilator for intensive care for adults, children, and infants with a body weight of at least 3 kg (6.6 lbs).

With SmartCare™/PS the EvitaXL is intended to stabilize the patient's spontaneous breathing in a "comfortable zone" and to reduce inspiratory support for adults and children with a body weight of at least 15 kg (33 lbs). The patients should be haemodynamically stable with adequate oxygenation and spontaneous breathing. SmartCare can be used for intubated or tracheotomized patients. Patients with body weight between 15 and 35 kg (33.1 and 77.8 lbs) must be endotracheally intubated and ventilated with active humidification.

SmartCare™/PS is contraindicated in case of severe COPD and severe neurologic disorder that effects the cerebral control mechanism of the spontaneous breathing pattern.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K051263

Indications for Use

510(k) Number (if known):

Device Name: EvitaXL with Option SmartCare

Indications For Use: The EvitaXL is a long-term ventilator for intensive care for adults, children, and infants with a body weight of at least 3 kg (6.6 lbs).

With SmartCare™/PS the EvitaXL is intended to stabilize the patient's spontaneous breathing in a "comfortable zone" and to reduce inspiratory support for adults and children with a body weight of at least 15 kg (33 lbs). The patients should be haemodynamically stable with adequate oxygenation and spontaneous breathing. SmartCare can be used for intubated or tracheotomized patients. Patients with body weight between 15 and 35 kg (33.1 and 77.8 lbs) must be endotracheally intubated and ventilated with active humidification.

SmartCare™/PS is contraindicated in case of severe COPD and severe neurologic disorder that affects the cerebral control mechanism of the spontaneous breathing pattern.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use

510(k) Number (if known): K 051263

Device Name: EvitaXL with Option SmartCare

Indications For Use: The EvitaXL is a long-term ventilator for intensive care for adults, children, and infants with a body weight of at least 3 kg (6.6 lbs).

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Description of the Device (Section 5)

This section provides information on changes that were made to the EvitaXL since the last Premarket notification: K051263 dated July, 12th 2005. (see attachment 5.1 in this section).

Intended Use

The intended use of the EvitaXL with SmartCare Option as cleared by FDA under # K051263 remains unchanged.

Specifications

The specifications of the EvitaXL with SmartCare Option as cleared by FDA under # K051263 remain unchanged.

Comparison to predicate device

All changes to the EvitaXL with SmartCare Option were developed, qualified, and reviewed in accordance with 'The Quality Systems Regulations for Designs Controls', and Dräger Medicals internal Product Development procedures. The changes were reviewed in accordance with 510(k) Memorandum #K97-1, 'Deciding When to Submit a 510(k) for a Change to an Existing Device', and a 510(k) rationale is on file for each project release.
No major changes be it technology, engineering, material, performance or labeling were made to the EvitaXL and the SmartCare option.

All of the above mentioned changes did neither change the overall performance or specification of the device EvitaXL nor the SmartCare Option, which led to Non-filing decisions for the changes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2005

Drager Medical AG & Co. KGAA
c/o Ms. Monica Ferrante
Director of Regulatory Affairs
Drager Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K051263
Trade/Device Name: EvitaXL with Option SmartCare
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: April 29, 2005
Received: May 16, 2005

Dear Ms. Ferrante:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 051263

Device Name: EvitaXL with Option SmartCare

Indications For Use: The EvitaXL is a long-term ventilator for intensive care for adults, children, and infants with a body weight of at least 3 kg (6.6 lbs).

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K051263

Proposed Device Labeling (Section 6)

The device labeling of the EvitaXL and the SmartCare Option in terms of instructions for use and device label (adhesives) is not changed. Thus the material is not included in this submission.

The promotional material included in the first SmartCare submission K#051263 remains in use unchanged and is not included in this submission.

The changes covered by this submission refer only to the promotional material appended to this section. It comprises customer presentations, a print advertisement and an Excel spreadsheet called 'Hospital Flow Calculation Tool'.

Dräger Medical intends to create more promotional material based on the claims stated in this submission.

Summary of Claims

The claims made in the promotional material are summarized as follows:

Medical results:

- Increase efficiency and improve therapy to help accelerate healing
- Reduce ventilator induced injuries and complications
- Decrease potential for infections
- Avoid re-intubation
- Avoid infections and complications
- Increase of quality of outcomes

Time reduction:

- Reduce weaning duration to impact length of stay
- Reduce overall ventilation time by 33%
- Decrease ICU length of stay by up to 20%
- Reduce weaning duration by up to 50%
- Accelerate healing and reduce ventilation time
- Wean fast with SmartCare

Cost reduction:

- Impact the bottom line

The concrete presentation of the claims is shown in the appended slides

List of Appendices

Appendix 6.1:	Excerpt form Presentation "Impact"
Appendix 6.2:	Excerpt form Presentation "Integrated CareArea™ Solutions for Critical Care"
Appendix 6.3:	Excerpt form Presentation "Impact Solutions for Critical Care Ventilation"
	NOTE: The complete presentations listed under 8.1 - 8.3 cover a wide range of Dräger products. The excerpts included here comprise the SmartCare section of these presentations.
Appendix 6.4:	"Impact" Print Ad

Hospital Flow Calculation Tool

The calculation tool uses queuing theory to model patient throughput through a hospital or a single unit based upon admission requests, available beds and length of stay on the ICU.

The tool has neither diagnostic nor therapeutic inputs or outputs.

As potential ICU patients cannot wait for treatment, the allowed queue is zero. The simulation calculates the probability of the ICU being full and therefore the probability that patients that cannot be admitted due to full occupancy of the ICU have to be diverted to other hospitals.

Input parameters for the simulation are:
- admission requests
- available beds
- length of stay (on a monthly basis over 2 years)
- percentage of ventilated patients

The actual hospital data are modified allowing for the effects of SmartCare. The reduced length of stay results in an increased throughput for the ICU. This is shown by the main output parameters of the simulation:
- utilization (percentage of use of available beds)
- number of rejected patients per month
- length of stay of admitted patients.

These data are transferred into a business case calculation considering the coverage of fix costs of a day at the ICU, the revenues of additionally treated patients and the investment for SmartCare equipped devices. The impact on the financial result of the hospital is shown as the final result of the calculation.

NOTE:

For reviewing the tool please refer to the appended CD ROM. Install QTP (a package of Excel formulas for modeling queues) first. Open simulate final.xls.

List of Appendices

Appendix 6.5:	Presentation: Hospital Flow Calculation Tool (including screen shots)
Appendix 6.6:	Paper: "The Hospital Flow Diagnostic" Description for Excel based Calculation Tool
Appendix 6.7:	CD Rom with Hospital Flow Calculation Tool Contents: simulate final.xls (Microsoft Excel Spreadsheet) QTP 4.0 (necessary Excel Plug in)

(b)(4) Trade Secret Process - Product Specs

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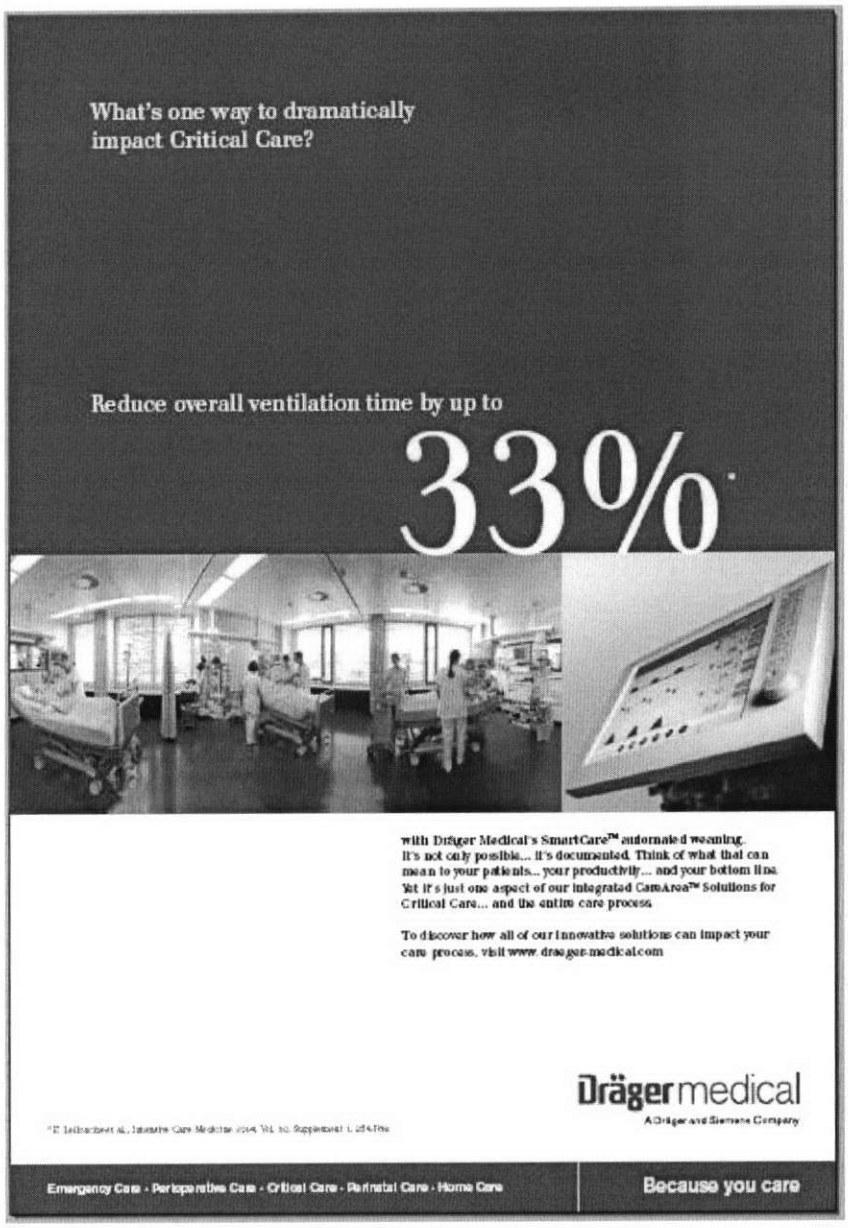
Appendix 6.4: "Impact" Print Ad

What's one way to dramatically impact Critical Care?

Reduce overall ventilation time by up to 33%

with Dräger Medical's SmartCare™ automated weaning. It's not only possible… it's documented. Think of what that can mean to your patients… your productivity… and your bottom line.
Yet it's just one aspect of our integrated CareAreaTM Solutions for Critical Care… and the entire care process.
To discover how all of our innovative solutions can impact your care process, visit www.draeger-medical.com

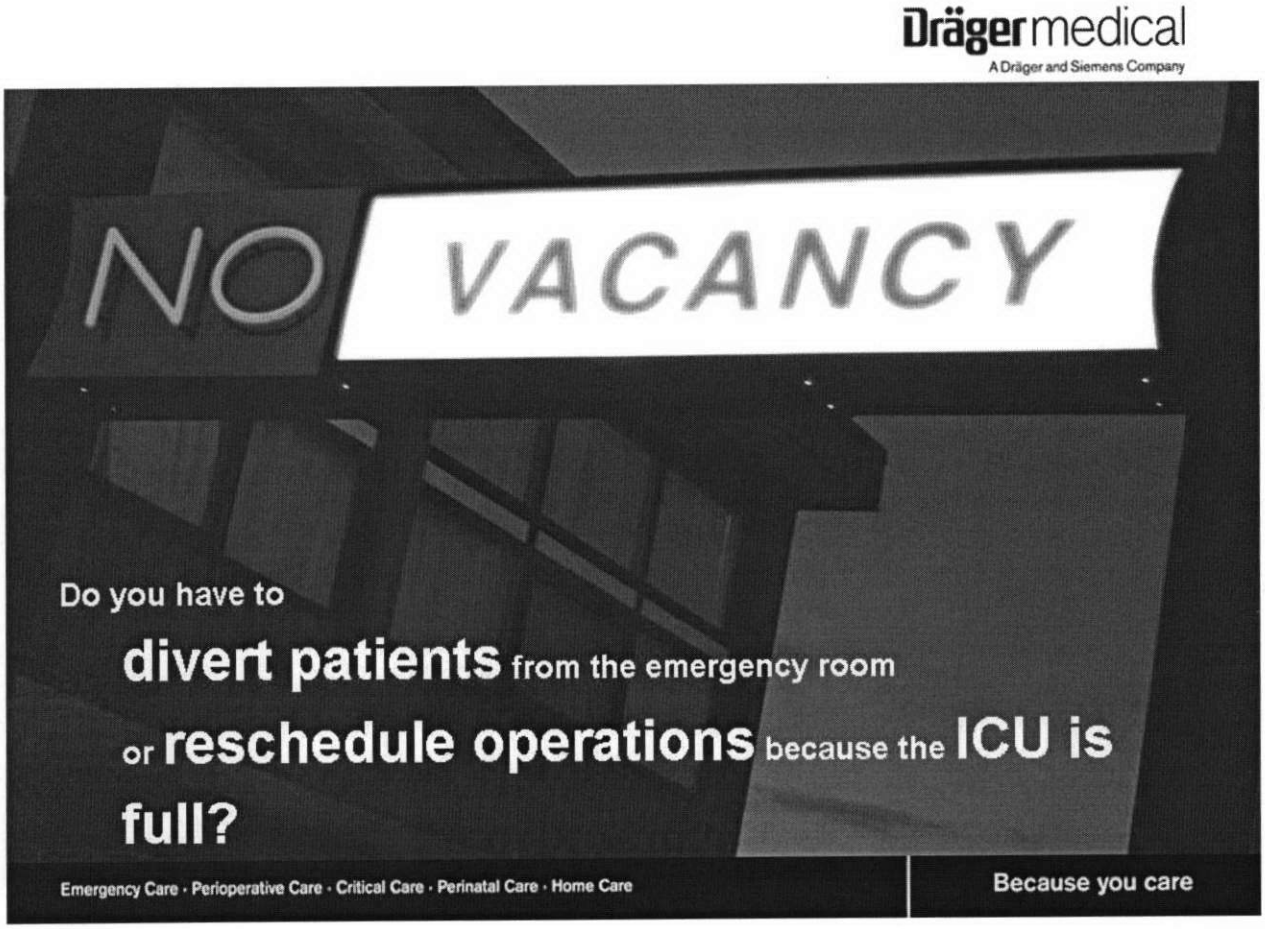
*F. Lellouche et al., Intensive Care Medicine 2004, Vol. 30, Supplement 1, 254:P69.



Appendix 6.5: Hospital Throughput Calculation Tool

The presentation contained in this appendix gives an overview on the calculation of ICU throughput with the Excel spreadsheet.

Pages that contain screenshots from the spreadsheet are marked with ***)XLS**.



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The Hospital Flow Diagnostic

The Hospital Flow Diagnostic describes a method for measuring hospital throughput and hospital activity based on bed turns. Hospital flow can be measured at several levels. Each level provides a portion of the total measurement picture.

- Patient and Community
- Hospital Throughput
- Hospital Activity
- Hospital Performance

The **Patient and Community** level demands the consideration of patient and community satisfaction. The actual measurements for these levels of satisfaction often are not available, but are inherently known by the hospital, patients and community. A methodology for this metric should be developed.

The **Hospital Performance** level will be measured by ICU, PACU and ED percent of capacity wasted to boarders, case mix adjusted LOS for nursing home patients, percent of patients leaving ED without being seen and percent of time on diversion will be used to evaluate the performance of the hospital.

The focus of this document is a method for measuring **Hospital Throughput** and **Hospital Activity** focusing on "bed turns". Bed turns can be looked at both with and without adjustment for acuity based on the case mix index.

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Performance and Testing Data (Section 7)

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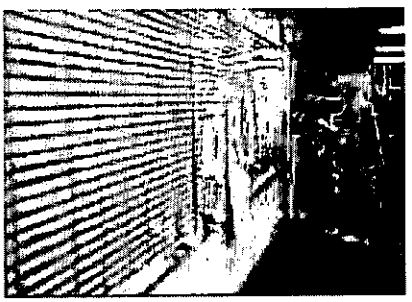
IMPROVEMENT



Innovation Series 2003

Optimizing Patient Flow

Moving Patients Smoothly Through Acute Care Settings

2

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We have developed IHI's Innovation Series white papers to further our mission of improving the quality and value of health care. The ideas and findings in these white papers represent innovative work by organizations affiliated with IHI. Our white papers are designed to share with readers the problems IHI is working to address; the ideas, changes, and methods we are developing and testing to help organizations make breakthrough improvements; and early results where they exist.

The Institute for Healthcare Improvement (IHI) acknowledges the contributions of:

Carol Haraden, PhD, Vice President, IHI
Tom Nolan, PhD, Senior Fellow, IHI
Roger Resar, MD, Senior Fellow, IHI
Eugene Litvak, PhD, Professor of Health Care & Operations Management,
Boston University School of Management
Members of IHI's IMPACT Network and Pursuing Perfection initiatives

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Telephone (617) 301-4800, or visit our website at www.ihi.org

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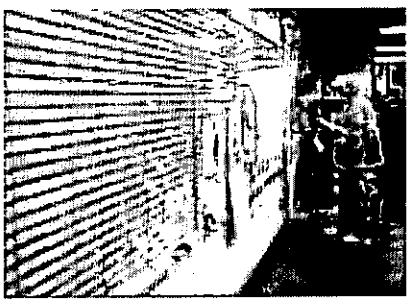

Innovation Series 2003

Optimizing Patient Flow

Moving Patients Smoothly Through Acute Care Settings

This paper is based on work funded, in part, by Pursuing Perfection: Raising the Bar for Health Care Performance, a national program supported by The Robert Wood Johnson Foundation with direction and technical assistance by the Institute for Healthcare Improvement.

Executive Summary

Because waits, delays, and cancellations are so common in health care, patients and providers assume that waiting is simply part of the care process. But recent work on assessing the reasons for delays suggests otherwise.

Optimizing Patient Flow is part of a series of innovative programs developed by the Institute for Healthcare Improvement (IHI) in Cambridge to help hospitals improve the care they provide patients. With the Optimizing Patient Flow program, IHI offers new perspectives on the impediments to timely and efficient flow of patients through acute care settings. The program offers a model for evaluating patient flow, testing changes for improvement, and measuring results.

IHI and approximately 50 hospitals have been working together to evaluate what influences the smooth and timely flow of patients through hospital departments, and to develop and implement methods for improving flow. Specific areas of focus include reducing waits for inpatient admission through emergency departments, achieving timely and efficient transfer of patients from the intensive care unit and the post-anesthesia care unit (PACU) to medical/surgical units, and improving flow from the inpatient setting to long-term care facilities.

While few hospital areas are designed to achieve optimal flow of patients, the emergency department, intensive care unit, and operating rooms and their related pre- and post-care areas tend to be major bottlenecks because they are non-interchangeable resources. Reducing delays and unclogging bottlenecks depends on assessing and improving flow between and among these departments, and throughout the entire system, rather than in isolated departments.

IHI believes that the key to improving flow lies in reducing process variation that impacts flow. While some variability is normal, other variation is not and should be eliminated. Hospitals working with IHI have tested a range of changes to reduce process variation and improve flow. These changes are described in this paper.

Introduction

Patients and providers alike regard waits, delays, and cancellations as a normal part of getting and giving care. Particularly in hospitals, waiting seems intrinsic and, to many, intractable.

Acute care settings are plagued with waits, delays, and diversions. Nowhere is this more observable and its impact more palpable than in hospital emergency departments (EDs). These are busy places, and getting busier.

In the United States, EDs experienced a 20 percent increase in patient visits over the past decade.[1] Not surprisingly, ED waiting times have also increased. According to the Centers for Disease Control and Prevention, the average wait time for non-urgent visits increased between 1997 and 2000 by 33 percent, from 51 minutes to 68 minutes.[2]

Diverting ambulances away from hospitals that are at capacity is another problem on the rise. An October 2001 government study in the US showed that "ambulance diversions have impeded access to emergency services in metropolitan areas in at least 22 states since January 1, 2000. More than 75 million Americans reside in the areas affected by these ambulance diversions."[3]

Examples abound, according to the study. "In Tucson, Arizona, so many hospitals diverted ambulances that paramedics had to struggle to find any place to bring patients. In the Boston area, ambulance diversions last year ran as much as ten times higher than in previous years. On some days in Atlanta, eight to ten hospitals diverted ambulances at the same time. In Los Angeles, two dozen emergency rooms at the heart of the area's emergency system were closed to ambulances almost one-third of the time in June 2001."[4]

The so-called "ED problem," however, is actually a system problem. EDs do not exist in isolation, but are part of a system of care through which patients flow. Increasing capacity in the ED to accommodate more patients, a solution chosen by many hospitals, is like broadening only the large end of a funnel. Increasing input without facilitating a smooth exit (in this case, transfer to other hospital units) worsens the problem.

In a recent report on ED crowding, the US General Accounting Office (GAO) noted the connection between the ED and the rest of the hospital system: "While no single factor stands out as the reason why crowding occurs, GAO found the factor most commonly associated with crowding was the inability to transfer emergency patients to inpatient beds once a decision had been made to admit them as hospital patients rather than to treat and release them.When patients 'board' in the emergency department due to the inability to transfer them elsewhere, the space, staff, and other resources available to treat new emergency patients are diminished."[5]

The units to which ED patients are often transferred must be viewed as integrated parts of the whole system. Most often EDs divert because the hospitals to which they are appended lack the space to move patients forward. A recent study of ED overcrowding showed that the primary reason hospitals go on diversion is the lack of available critical care beds.[6]

According to one expert, "...the frequency of ambulance diversion now correlates better with total occupancy than with ED volume. Increasing average occupancy levels, particularly in specialized units, often become a constraint leaving less room for unscheduled admissions. Admissions through the emergency department must be diverted, denied, or placed in a line or queue. As this pattern continues, the quality of care declines as all patients are increasingly placed into holding patterns."[7]

The costs of delays in care are many, including these:

- The ED becomes an inappropriate and expensive holding area when patients are not transferred to an inpatient unit in a timely manner. "Parking" patients in hallways to await transfer is an issue affecting service, care, and safety.
- When the ED is overcrowded because patients cannot be transferred quickly to care units or operating rooms, incoming patients can experience harmful delays in receiving care. Some even leave without being treated.
- Patients waiting to be transferred from the ICU to a patient care unit represent not only a service but also a cost issue: the ICU is a very expensive place to wait.

When surgical schedules back up, patients and providers are affected across the continuum of care.

Techniques that are used to manage ED flow itself will not have a strong impact on either hospital diversion rates or manage the problem of patients being "boarded" in the ED as they wait hours for an inpatient bed.

Waits and delays, bottlenecks and backlogs, are not the result of lack of effort or commitment on the part of staff. These problems cannot be solved by working harder. Rather, they illustrate what Donald M. Berwick, MD, MPP, President and Chief Executive Officer of the Institute for Healthcare Improvement, calls the first law of improvement: "...[E]very system is perfectly designed to achieve the results it achieves."[8]

The answer to improving flow of patients lies in redesigning the overall, system-wide work processes that create the flow problems.

Optimal care can only be delivered when the right patient is in the right place with the right provider and the right information at the right time. Improvement efforts in hospitals around the US are showing that it is possible to reduce waits and delays in hospital care, improving the flow of patients and information throughout the care system. The results of improving flow can include increased access, shorter waiting times, lower costs, and better outcomes.

Background

The Institute for Healthcare Improvement has been working with approximately 50 hospitals in the US and the UK in a year-long collaborative project to improve flow through acute care settings. An additional 100+ hospitals are also addressing the issue as part of IHI's IMPACT network, a group of change-oriented health care organizations committed to ambitious levels of improvement on a broad scale.

Through this work, hospitals have been testing the theory that the key to improving flow throughout the acute care setting lies in understanding the variability throughout the hospital system. This work focuses chiefly on the variation in waits, delays, and cancellations that occur when capacity does not match demand. Capacity and demand may match *on average*, and on paper it may look as though the system ought to flow smoothly. Indeed it will, if demand (patients) flows in predictably and capacity (staff) is ready to manage it. *However, even when capacity and demand are matched on average, the degree of variation in the timing of the arrival of patients (demand) and the ability of the staff (capacity) to absorb that demand results in waits, delays, and cancellations.*

Developing the ability to shape, predict, and manage variability and to allocate resources appropriately at the front line of care can improve patient outcomes, increase staff morale and retention, reduce costs, and improve quality of life for both patients and caregivers.

IHI's Challenge for Hospitals

The Institute for Healthcare Improvement has developed a process and methodology for hospitals to use in evaluating and improving patient flow in acute care settings. As part of its effort to foster improvements throughout the health care system, IHI invites hospitals to engage in this process, using the methods described in the following sections.

Step 1: Evaluate Flow: How Much of the Time Do You Get It Right?

The first step in evaluating the flow of patients through your acute care setting(s) is to find out, on average, how much of the time your hospital "gets it right" in moving patients through the system in a timely and efficient manner. In considering this question, your hospital needs to look at both the frequency of "parking" patients (i.e., keeping or placing admitted patients in a "holding" location—sometimes in the ED, sometimes simply in a hallway—when they cannot be moved immediately to their intended bed or location) and hospital occupancy as key indicators.

Two key questions help bring these issues into focus:

1. Do you "park" more than 2 percent of your admitted patients at some time during the day at least 50 percent of the time?
   Example: In a hospital with a midnight census of 500 patients, 10 patients (2 percent) were "parked" during the day, waiting for admission to the final destination bed. This occurs more than half the time during the sample period.

2. Does your hospital have a midnight census of 90 percent or more of your bed capacity more than 50 percent of the time?
   Example: A 500-bed hospital had more than 450 patients in the hospital at midnight (90 percent of capacity) more than half the time during the sample period.

If you answer "yes" to one or both of these questions, your hospital is likely struggling with flow problems on a regular basis. "Parking" patients is a clear indication that the system is inhibiting the smooth forward movement of patients to their appropriate destination. And if your midnight census is typically high, you probably experience capacity problems, since your hospital is virtually full at the start of the day, leaving little capacity for new admissions. To address these issues, you will have two tasks: working to reduce flow variation *and* "extending the chain"—that is, working with others along the continuum of care, including those outside your hospital, to smooth the flow of patients into and out of your organization.

Even if you answer "no" to both these questions, you may still feel that patients do not consistently move smoothly through the system. This may indicate a need to reduce flow variation (described in the next section).

Action: Evaluate patient flow by reviewing occupancy and "parking" of patients.

Step 2: Measure and Understand Flow Variation

Variation is intrinsic in health care. It is the result of clinical variability (number of patients presenting with certain clinical conditions), flow variability (the ebb and flow of patients arriving throughout the day), and professional variability (the variation in skill levels and techniques among providers). Eugene Litvak, PhD, Professor of Health Care and Operations Management and Director of the Program for Management of Variability in Health Care Delivery at the Boston University School of Management, has suggested that only the following scenario would eliminate variability:

1. All patients have the same disease with the same severity.
2. Patients arrive at the same rate every hour.
3. All providers (physicians and nurses) are equal in their ability to provide quality care.[9]

Some kinds of variability (so-called "random variability") cannot be eliminated, or even reduced; they must be *managed.* This is true of patient variability. We cannot eliminate the many types of problems from which patients suffer, nor can we control when they arrive in the emergency department.

Other types of variability ("non-random"), on the other hand, are often driven by individual priorities, resulting, for example, in surgical schedules that are heavy on Wednesdays but light on Fridays due to surgeons' preferences rather than actual demand. Non-random variability should not be managed; it should be *eliminated.*

Volume, census, and occupancy rates are often calculated and displayed as means or averages. However, it is the *variation* in these metrics that causes most of the flow problems in our hospital systems. Consider this example: The *mean* elective surgical volume for two hospitals for one week may be 125 patient cases each. Hospital A has a steady flow of surgical cases throughout the week, allowing for optimal scheduling and predictable demand for staffing and patient beds. Hospital B, which also has a mean of 125 cases, schedules 50 percent of its cases on Mondays and Wednesdays, and 50 percent on the remaining days. Because the caseload is so high on Mondays and Wednesdays, there is no room for the seemingly random but historically predictable surgical complications and added cases. The demand for staff, beds, and equipment is at a maximum. Any added volume or decrease in capacity is felt quickly as waits, delays, and cancellations.

Another helpful exercise is to look at the variation in census *between* each day of the week and the variation in census *within* each day. These measures often point to different problems and solutions.

Action: Measure and evaluate variability from all sources. Display the full range of the variability of measures like waiting times and daily surgical volume.

Step 3: Test Changes to Improve Flow

Hospitals that want to improve flow should consider testing two main groups of changes:

1. Changes that can be made within the hospital; and
2. Changes that result in cooperative relationships with other health care providers outside of the hospital.

1. Changes Within the Hospital

Smooth the Surgical Schedule

The surgical schedule is a major source of variation in flow. Several methods are showing early promise in smoothing the surgical schedule and making it more predictable, including the following:

- **Smooth the number of elective scheduled cases and case hours per working day.**
  Scheduling the maximum number of elective surgeries into the schedule, even just on some days, leaves little flexibility for emergency surgeries. If your unscheduled surgery time currently averages 10 percent or more, adequate space should be left in the surgical schedule or you will routinely experience untenable waits for some surgical patients.

- **Designate separate ORs for scheduled and unscheduled surgeries.**
  Since the vast majority of surgery is scheduled, most of the OR space should be so assigned. Utilization of the scheduled rooms then becomes predictable and controllable, and wait times for unscheduled surgery become manageable. Concerns about the cost of designating a surgeon strictly for emergencies are unwarranted, compared to the cost of canceling and delaying scheduled surgeries when an emergency surgery disrupts a day's elective schedule.

Schedule the Discharge

Admission bottlenecks are often created because discharges are not managed efficiently. Creating a more consistent and predictable discharge schedule can help improve flow. Some change methods include the following:

- **Provide a process for scheduling the date and time that patients will be discharged at least one day in advance.**
  Although the date and time of discharge may be uncertain for some patients one day in advance, the usual hospital system behaves as if this were the case for all patients. In fact, early data indicate that nurses, doctors, and other health care providers can usually predict one day in advance which patients will be discharged the following day with more than 80 percent accuracy. They can predict with less accuracy which patients will be discharged the day after that and so on. However, in most cases this knowledge is not used to optimize, plan, or synchronize the work of discharging patients. This work will most likely require a centralized planning and scheduling function. Planners can record data about the ability of the system to comply with the schedule and can document reasons for noncompliance to identify bottlenecks and processes needing improvement.

- **Orchestrate the discharge.**
  A set series of tasks must occur prior to discharging a patient. These tasks include examination and sign-off by appropriate providers and patient education. For each patient, the time of discharge and the tasks that need to be performed and in what order will be provided one day ahead of time. This allows all responsible persons to schedule their work accordingly.

- **Provide a process and a team for discharging patients with more complex issues, using data from discharge coordinators.**
  Because of the condition of their health, lack of support, or psychosocial problems, some patients are difficult to place in appropriate settings after discharge. Although the time and date of discharge should be scheduled as for other patients, the orchestration of the discharge of these patients should be handled separately from the normal flow of patients. A special team that is capable of crafting customized and unusual solutions to meet the needs of these patients should do the orchestration.

- **Synchronize other movements to the discharge schedule.**
  Once a discharge schedule is in place, internal transfers of patients, such as from an ICU to a patient are unit, can be synchronized to that schedule. Individual units can begin scheduling and orchestrating movements of their patients at a local level. This synchronization allows local, unit-level control and system-wide optimization to occur simultaneously.

2. Changes Involving Providers Outside of the Hospital

"Extend the Chain" of Flow Improvement

Responsibility driven by geography—that is, addressing only those problems in one's own area—is the source of much variation in hospitals. Particularly for hospitals with patient flow problems, working with physicians and long-term care facilities—those with the power to impact both admissions and discharges—is an effective strategy to improve flow.

A common bottleneck in the ICU, for instance, is the inability to transfer chronic ventilator patients off the unit because there are not enough ventilator beds in other settings. One hospital solved this problem by partnering with an unaffiliated nursing home. The nursing home was able to open a ventilator unit because the hospital assigned an intensivist to serve as a part-time medical director for the unit. This helped improve flow out of the ICU and provide predictable income for the nursing home, and also resulted in high-quality, lower-cost care for the patients.

Other methods of "extending the chain" include promoting advanced access scheduling (sometimes referred to as "open access") in physicians' offices so patients can get timely access to ambulatory care in an appropriate setting, rather than resorting to the hospital ED, and working with hospice services to assure that end-of-life care is provided in the most appropriate, but least intensive, setting.

Action: Select and test the changes that seem to hold potential for improving flow, both within the hospital and with providers outside of the hospital, based on your evaluation of flow variability.

Conclusion

Understanding patient flow requires looking at the whole system of care, not just in isolated units. Reducing variation in flow has been shown to improve overall patient flow. Providing patients with timely access to appropriate care is an essential element of high quality care, because *when* care is provided is often as important as *what* care is provided.

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The savings potential of innovative medical technology in healthcare

Berlin 2006

Offprint March 2007

Complete Study available at Spectaris, Berlin (Germany)

A collaborative study by

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Preface

Medico-technical advances open up many new options for diagnosis, treatment, and therapy, and thus have a positive effect on the quality of life of each individual.

If, for example, a modern procedure can cure a once incurable disease, there are direct costs arising from its use. Whether or not society wishes to incur the cost is certainly an ethical question, one that will not be addressed here. In connection with these costs, however, medical technology is in many cases portrayed as the cost-driver in healthcare. However, there is often a failure to differentiate between medico-technical advances and medical technology. Furthermore, it is frequently overlooked that the expenditure for medical technology as a percentage of overall healthcare costs tends to be low.

In addition, the indirect costs savings resulting from the prevention or cure of diseases as a result of the new procedure is likewise often overlooked. Because factors such as faster recovery time, physical inviolability and quick reintegration into work or normal life are difficult to quantify and the cost savings often fall in areas outside of healthcare in studies on the national economy, a fully informed debate on costs is rare or rudimentary. Also often left out of the picture is that new methods of diagnosis and treatment drop in cost with more widespread use and are therefore more accessible to the general public.

Besides these difficult-to-quantify factors, however, there are factors that are measurable and demonstrate that innovative medical technology can bring about cost savings. This is especially true for direct costs, whereby existing diagnosis, treatment, and therapy options improve through the latest technology and become more efficient. This includes shorter surgery times, shorter hospital stays, reduction in personnel costs and less materials use.

To finally shed more light on this last area of potential cost savings through innovative medical technology and give new impetus to public discussion, this study was prepared by Prof. Dr. Marc Kraft of the Department of Medical Technology of the Technical University of Berlin and a team from the Medical Technology Competence Center of the Droege & Comp. Management Consulting Firm under the direction of Dr. Björn Schlosser in cooperation with SPECTARIS. Using various products as examples, potential cost savings in healthcare were identified. It is further shown that process innovations in the clinical field can help realize savings potential.

We hope you find the material thought-provoking and that the often one-sided cost debate will become much more open. All discussion on costs and savings should always take into account that the healthcare industry is and will remain one of the most important branches of the German economy, employing well over 4 million individuals, i.e. over 10% of workers in Germany. Almost 90,000 individuals are employed in the medical technology industry alone.

Sven Behrens
CEO SPECTARIS e.V.

The financial impact of innovative medical technology with savings effects in healthcare

Marc Kraft, Department of Medical Technology,
Technical University Berlin

(Shortened version)

The basic conditions

Healthcare spending in Germany has risen continuously over the last several years. In 1993, the figure stood at 168 billion euros; by 2003, the figure had risen to 240 billion euros, an increase of nearly 43%. In that same time frame, the gross domestic product grew less, which meant that healthcare costs as a percentage of the gross domestic product rose from 9.9% to 11.1% in 2003[1]. That is 2.5 percentage points higher than the OECD average of 8.6%[2]. It is clear that this trend is an economic challenge against the background of the expected demographic changes, with fewer paying contributors and the growing number of retirees. Nonetheless, the positive growth of our national economy can be viewed as the success of the expansion of the healthcare market, whose growth contributes positively and substantially to the overall balance sheet[49].

The right to „care of the insured commensurate with the generally recognized level of medical knowledge" that is anchored in social legislation is squarely up against increasingly limited financiability. §70 of Book V of the Social Code also stipulates: Care of the insured must be adequate and appropriate without going beyond the necessary and must be provided at the level of quality professionally provided and cost-efficiently. The introduction of the Diagnostic Related Groups (DRG[1]) is intended to support this imperative for cost efficiency by having health insurers reimburse a fixed, treatment-dependent amount rather than the actual cost of medical treatment. Healthcare providers who succeed in implementing cost-efficient and effective medical procedures at the same or even higher quality realize a profit from the difference between the actual cost and the fixed reimbursement.

Providers who do not work efficiently will not be able to survive the increasing competition in healthcare over the long term. The limits of „level of quality professionally provided" are not clearly definable today and change constantly with increasing medical knowledge and capabilities provided by medical technology. To ensure care of equal and even better quality within the same financial confines, treatment must become more efficient. All possibilities for realizing savings must be exhausted; and

[1] Diagnosis Related Groups

[1] see references on pg. 14ff.

innovation in medical technology can certainly contribute. This study provides evidence for this based on specific product examples.

To curb the rise in healthcare costs or to control their trajectory, it is necessary to understand the source of those costs. Numerous scientists have taken on this task in the past. The following provides a brief sketch of just how contradictory the results are. In its 2003 report „Financing, User Orientation and Quality", the Expert Advisory Board for Concerted Action in Healthcare stated that the basic determinants of healthcare cost trends the world over can be divided into factors of supply and demand[3]. Supply-side factors include supply-induced demand, progress in medical technology, a negative price structure effect and the increasing propensity toward defensive medicine[2]. On the demand side are such factors as evolving demographics, change in the disease spectrum and individuals' own sense of entitlement and level of utilization. The experts noted that of these determinants, most attention in science and public policy is being directed to progress in medical technology and the percentage of costs attributable to demographics. The views on how these factors influence price trends are very different. Braun et. al. noted that supply- and demand-side factors are each weighted so differently that it would be misleading to consider them of equal value[4].

Medical technology and medico-technical progress

The goal of this study is to investigate the impact of innovation in medical technology on healthcare. As a part of „medico-technical progress", innovation can contribute to reducing costs and increasing effectiveness in healthcare, a topic to be presented and discussed here using specific examples. Because of the lack of sufficient data, however, it is impossible to produce a consolidated balance sheet of the financial impact of medico-technical innovation on healthcare costs.

To understand the role of medical technology within the context of „medico-technical progress", an explanation of terms is first necessary. Medico-technical progress includes advancements in medicine, pharmacology, nursing, organizational processes, general and medical technology. It is quite helpful to examine these different areas more closely, especially since the terms „medico-technical" and „medical technology" are rarely sufficiently disentangled. Purely medical advances (e.g. new knowledge of disease progression with the potential of developing new treatment strategies) do not always require support from technology.

On the other hand, there are technical advances in all areas of life that indirectly contribute to the increase in healthcare costs even though they have no direct medical application. Information and communication technologies, for example, significantly influenced the awareness level of new diagnosis and treatment options among physicians and in the general population, in turn having an implicit effect on their use. The growth and impact of technology, however, is not attributable to medical technology in the narrower sense.

They are defined in the medical device law[7]. Concisely put, they serve individuals in the treatment of illness, injury or impairment, influence anatomical structure or a physiological process or conception, and have primarily a physical effect. In addition to standard medical devices, such as X-ray systems, dialysis machines, endoscopes and blood pressure meters, medical products also include bandaging materials, single-use injections, etc. Medical technology is therefore a subset of medical products, although drawing the line between the two is difficult. The

[2] Medical steps physicians take to offset the threat of patient claims

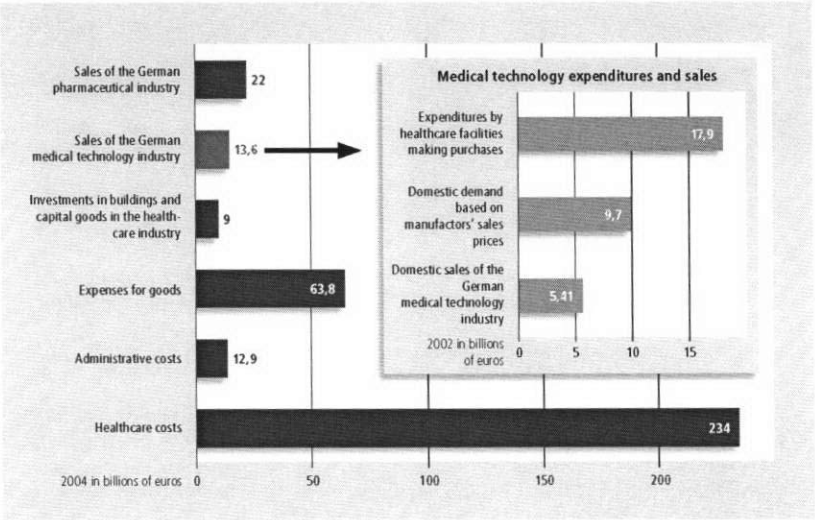

Fig. 1. Relationship of healthcare outlays and medical technology expenditures and sales in Germany[3]

German Society for Biomedical Technology defines medical technology as the use of technology in medicine[8]. This includes the use of resources and methods from the engineering and natural sciences on living systems in research and development as well as the medical consulting process (prevention, diagnosis, treatment, rehabilitation, after-care). The medical technology industry itself can be further delineated through a firm's association with professional organizations and its participation in relevant trade fairs.

Outlays for medical technology

Sales statistics can serve as the basis for annual medical technology outlays as a percentage of total healthcare expenses. For 2006, sales predictions for the German medical technology industry amount to 16.3 billion euros[9]. In 2005, the figure was just 14.72 billion euros. In contrast, sales in the German pharmaceutical industry totaled 23.7 billion euros in the same period (161% of sales in medical technology)[11].

Domestic sales by the German medical technology industry will hit approx. 5.7 billion euros in 2006[9]. After years of stagnation and decline, sales will regain 2003 levels[12]. Three years ago, domestic sales represented 2.4% of total expenses for healthcare. However, the expense balance sheet must also include the sales of foreign companies within Germany. In a study by the German Federal Ministry of Education and Research (BMBF), there are two approaches used to quantify domestic demand for medical technology products. If based on sales production and foreign trade figures of suppliers using manufacturers' sales prices, the total for the year 2002[4] is just under 9.7 billion euros[14]. However, estimated outlays for medical technology by healthcare facilities in Germany total 17.9 billion euros, nearly twice as high, as evidenced by a demand analysis based on purchase prices. The differences arise from the differences between the service providers' purchase price and the manufacturers' sales prices (commercial mark-up) and posting and related depreciation of capital goods[16].

[3] Data sources as cited in text

[4] DIW reached the same conclusion in its study [15]

The outlays for medical technology on the demand side make up 7.6% of expenses for the healthcare system in 2002[5].

This quantitative analysis alone leads to the conclusion that expenses for acquiring medical devices are not a major cost factor in healthcare. Other types of services make up a significant portion of healthcare costs: in 2004, costs for physicians' services were 63.8 billion euros (27.2%), ahead of expenses for „goods", which include medical devices and technology. Administrative services alone made up 5.5% at 12.9 billion euros[6].

However, the conclusion should not be drawn that all sales of goods in healthcare can be attributed to technical progress; the major portion of the expenses really comes from less innovative products. In 2002, the highest percentage of domestic demand, at 15%, went toward „dental materials, devices, and systems", two-thirds of that for dental prostheses alone[14], without any fundamental changes in treatment over recent years.

Evaluation of medico-technical progres

In assessing overall medico-technical progress (including the percentage of medical technology products) as a potential cost factor in healthcare, the literature describes a number of different views[20]. According to Henke, medico-technical progress is, next to demographic changes, the second major driver of trends of healthcare costs[6].

New technologies can add to the cost burden if they do not replace existing technologies but are used in addition to them. Even in individual cases where the new technology brings treatment costs down, it can be accompanied by an overall increase in costs if previously untreatable patients are treated and incur (follow-up) costs.

Even in the early introductory phase of new technical developments in medicine, costs can increase[23], because when innovations are initially distributed they are often more expensive than at a later phase, when costs come down due to economies of scale and technological improvements[15]. A current DIW[20] study notes in this context that innovations can lower indirect costs[7] (e.g., through process improvements at the hospital level or at the transsectoral level: inpatient/outpatient) often only after the technology comes into wider usage. The reason for this is the (prerequisite) structural or personnel changes.

Medical technology is one of the most innovative industries in Germany[48], so cost trends during market introduction are highly relevant for public awareness. The innovative strength of the medical technology industry is evident, among other things, in that investment in research and development, at 8%, is twice as high as the industry average and that the companies realize more than half of their sales from products that are no more than 3 years old[19].

The innovations are primarily concentrated in the following areas:

- improved diagnostics for early detection of internal injuries,
- treatment procedures that ensure an optimal healing process with a minimum of stress on the patient,
- the replacement and support of damaged organs, bones or joints by artificial, in part controllable elements,
- faster exchange of information and cost efficiency[17].

In the current BMBF study[18], technological innovation in medicine is summed up in three basic observations:

- medical devices are getting smaller all the time (miniaturization),
- there is increasing linkage with electronic data processing (computerization),

[5] Current calculations are not available to the author and not contained in the current studies by the DIW and BMBF on medical technology in Germany

[6] Federal Office for Statistics: „Health – Expenditures, Costs of Illness and Personnel in 2004"

[7] To calculate indirect costs, the loss of resources as a result of morbidity (inability to work) and premature mortality are identified, which is measured by the amount of loss of human labor and general ability to function. However, direct costs are determined by the use of resources for prevention, treatment by physicians, rehabilitation and nursing care [44]

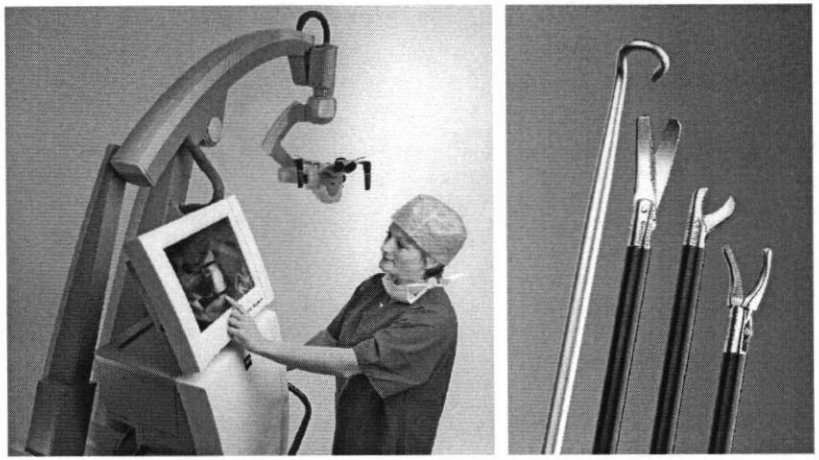

Fig. 2. Surgical microscope and instruments for minimally invasive surgery

- the view is shifting to the molecular and even the atomic level (molecularization).

Precisely because new developments arouse such interest in the public, but reduce costs only after broad introduction, as explained above, the dynamics of innovation quickly create the impression that overall costs are rising. The BMBF study[26] already cited concludes: „The economic analysis of long-term, fundamental innovations in healthcare will probably not be substantially improved even with much more effort. Visions cannot be placed on the scale."

Medico-technical progress is credited with the ability to lengthen people's lives. But this desired effect would also cause costs to increase. The literature disagrees on the extent to which there is a relationship between closeness to death and increased healthcare costs, however. Some authors see a positive relationship between age and healthcare expenses[e.g. 6].

According to the so-called medicalization theory, healthcare costs increase with rising age because morbidity and frequency of illness within a population group increase with age. Accordingly, the expense profile increases with advancing age[28]. The so-called compression theory[29] argues that healthcare costs jump shortly before death. Higher life expectancy, therefore, is not associated with higher average expenses for healthcare services[28]. One case study[30] showed that the major portion of costs during the final year of life went toward high-tech acute-care treatment of the younger group of older patients (ages 65 to 79) or patients with good functional status. The medical expenses for the younger of the elderly patients would be higher than for the older ones, because the burden of their extreme treatment is far greater[31]. There is not sufficient evidence to support either theory[28]. Changing demographics, therefore, cannot be unequivocally identified as the source of the rising need for support from medical technology.

Physicians, and not patient demand or the products offered by medical technology firms, are also ascribed a key role for the scope of services provided. According to Evans[22], in the industrial countries of the West, each year approx. 30% of costs are incurred by 1% of the insured, and nearly 60% of the total costs are incurred by the 5% of insured with the highest costs. The decision on the expenses incurred (incl. those associated with the use of technology) for these seriously ill, often hospitalized patients, lies almost exclusively in the hands of specialized physicians.

This raises ethical questions as well. The advances in technology and medicine broaden the range of options available for physicians to treat patients. It is in critical or life-threatening situations that costly measures are taken without full consideration being given to the economic consequences. Since physicians have taken an oath to be guided in their actions for the benefit of the patient, this problem can certainly not be solved.

In the interest of a balanced accounting of the financial impact of medico-technical progress, costs should not be the sole basis of measurement; the benefits must also be included[33]. Braun et. al. conclude that there are numerous examples for the cost-saving potential of developments in medical technology. One prime example for later savings through new technology is cited in a DIW[15] study, namely Lewis'[35] screening for colorectal cancer that identifies non-malignant polyps before colon cancer can develop. It is estimated that the introduction of the screening can result in cost savings of up to 75% over previous treatment costs. The goal of this study is to point out other, very current examples of the direct and indirect savings potential of innovative medical technology.

The consideration of saving indirect costs through medical technology innovation is extremely important in this context[24], even though quantifying such savings is usually very difficult. Henke[6] and others write that the benefits from factors such as longer life span and period of employment, improved quality of life, better physical performance and effects on overall economic growth should be taken into account. The cost-benefit analyses by Cutler and McClellan[25] are often cited in this context. The studies compared the rise in costs brought about by progress with its benefits for selected indications. They conclude that for the four indication areas studied, the estimated benefit clearly outweighed the rise in cost. This included the treatment of heart attack, depression, and cataracts and medical care of premature newborns, whereas the cost and benefits are approximately the same in the treatment of breast cancer. A study published by American hospital, physicians, and manufacturer associations emphasizes that the value of the improved health of the population over the past 20 years significantly outweighs the expenditures required[50].

The German Agency for Health Technology Assessment (HTA) of the German Institute for Medical Documentation and Information (DIMDI) has an important role in the objective evaluation of specific medical technologies. HTA reports serve the standardized and targeted analysis, synthesis, and evaluation of scientific data on the impact of medical technologies on health[32,47]. The analysis is conducted on the basis of the best available current evidence and often includes economic aspects as well as medical. In the face of today's rapidly advancing knowledge, however, their conclusions can be considered valid for just a short period of time. Furthermore, up until now only a relatively small number – 94 – of health technology assessments on selected topics have been performed[8]. The most reports, 24, were on the diagnosis and treatment of diseases of the circulatory system, followed by 22 reports on cancerous diseases and 11 on the diseases of the nervous system.

Examples of cost-savings potential of innovations in medical technology

This study is based on a survey by SPECTARIS - German Industry Association for Optical, Medical, and Mechatronic Technologies e.V. of major medical technology firms in Germany. The companies were asked what products and procedures contributed to cost reduction in healthcare either directly, as the most cost-efficient product or procedure, and/or indirectly or over the medium/long term.

[8] Number in the http://gripsdb.dimdi.de database in October 2006

Approximately 50 responses were received. To provide a concise overview, even to the lay reader, ten of the products on the market were selected. In selecting the products, it was important to include newer ones that were already seeing some success or whose market success was extremely likely as well as products already established in the market.

The spectrum of examples was to include highly complex to simply constructed medical devices from both larger and smaller companies. A telemedicine platform awaiting market introduction in Germany after the scientific studies at the time were concluded was added as the eleventh example. The implementation and spread of telemedical consultation for the chronically ill will be extremely important in the future. This additional product is intended to represent a development trend even though its precise savings effect is not calculable today.

The following examples of cost-saving and efficiency-boosting innovations in medical technology were selected:

- a drug-eluting stent for coronary arteries (annual volume of savings in Germany through interventional treatment of coronary artery disease in a high-risk group of diabetic patients: approx. 26 million euros)
- a surgical cutting system for minimally invasive tissue removal (annual savings volume in Germany through use in hysterectomy: approx. 22 million euros)
- a system for sure surgical sealing of blood vessels through patient protective tissue fusion (annual savings volume in Germany for use in hemorrhoidectomy, hysterectomy and strumectomy: approx. 31 million euros)
- a surgical microscope for spinal surgery (annual savings volume in Germany through use in minimally invasive spinal and back operations: approx. 33 million euros)
- a system for rapid weaning of acute-care patients who need ventilation (annual savings volume in Germany through reduction in material and personnel costs: approx. 648 million euros)
- a device that automatically determines the respiration pressure required to treat sleep apnea (annual savings volume in Germany through the reduction of personnel expenses in the sleep lab: approx. 6.67 million euros)
- a ready-to-use membrane filter for showers and faucets to protect against infections in hospitals (annual savings volume in Germany through reduction of material costs: approx. 12 million euros)
- a water-saving connector of the vacuum unit of a steam sterilizer to a customer-provided cooling circuit (annual savings volume in Germany through reduction of operating costs of suitable sterilizers: approx. 500,000 euros)
- a compact laboratory analysis system for cost-efficient HIV monitoring (annual savings volume in Germany through less costly patient tests: approx. 11 million euros)
- an orthopedic device for accelerated treatment of calcaneus fracture (annual savings volume in Germany through early mobilization of the patient: approx. 80 million euros).

Safe and cost-efficient treatment of ventilation patients

This study also addresses technologies classified in intensive care medicine and anesthesia. Over 50% of all patients in the ICU are artificially ventilated. Treating these patients is often protracted and cost-intensive. In particular, weaning the patient from the ventilator through a manual, gradual reduction of the ventilation pressures at the device is extremely time-consuming and risky for the

patient. Personnel need to monitor the patient to make sure his or her breathing remains stable without this support. The SmartCare/PS System from Dräger Medical is integrated into the ventilator and performs this process automatically. Savings are realized mainly by reducing the patient's hospital stay by 2.6 days and the avoidance of otherwise necessary medications and consumables valued at 2,000 euros.

Conclusion

The contribution health makes to work productivity and economic growth is rated higher in some economic studies than the contribution of education[45,46]. If the state of the population's health is key for economic growth[43,44], innovative medical technology is an essential foundation for economic development. In individual cases and when new technologies are introduced, the unavoidable increase in cost is often accompanied by a benefit that is not always immediately quantifiable because the cost savings are indirect. Even if the introduction of innovative medical technology has „only" a medical benefit and not an economic one, it is and remains meaningful and worthwhile to the affected patient[25, 42]. Medical technology helps save lives.

The current study uses reproducible examples to prove that in many cases direct and indirect costs savings in healthcare can be realized through the use of innovative technologies. A consolidated balance sheet of the financial impact of new developments in medical technology cannot be produced on the basis of this product sampling. However, the study does help objectify the discussion about the role of medical technology within the framework of the advances in medical technology as a prerequisite for an objective analysis.

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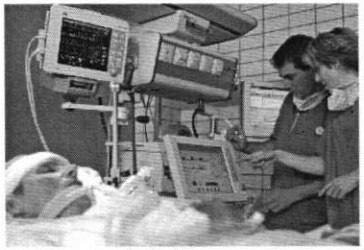
Examples of innovative medical technology with savings potential

- Example 5:
  Dräger Medical AG & Co. KG: „SmartCare®/PS"

Example 5: Dräger Medical AG & Co. KG: „SmartCare®/PS"

System for rapid weaning of ICU patients who need ventilation



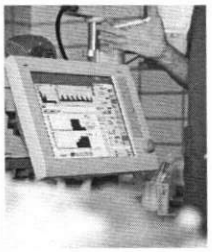


Fig. 5.1., 5.2 Use of Evita XL ventilator with the SmartCare/PS System

Overview/Product Description

Introduction/Ranking

Over 50% of all patients in the ICU are artificially ventilated. Treating these patients often proves to be protracted and cost-intensive. It often takes a long time to wean patients from the ventilator, in particular. Medical guidelines and protocols that define patient treatment and lead to shorter weaning times, however, have not been universally established. One reason is certainly due in part to the increased workload associated with implementing the protocols. The automation of this procedure promises a clear improvement in the quality of treatment of the ventilated patient. The resulting reduction in the treatment period increases the cost-efficiency in the artificial ventilation of patients.

A Collective Task Force Facilitated by the American College of Chest Physicians, the American Association for Respiratory Care, and the American College of Critical Care Medicine 2001; „Evidence-Based Guidelines for Weaning and Discontinuing Ventilatory Support", Chest VOLUME 120/NUMBER 6/DECEMBER, 2001 Supplement

Area of Application

The SmartCare/PS System automates the procedure for weaning ventilated ICU patients from the artificial ventilator on the basis of a clinical protocol. It is designed to keep the individual ventilator period as brief as possible. The protocol uses comprehensive medical knowledge (experts, user knowledge) to automatically adjust the parameters of the artificial ventilation to the recovery of the patient.

Function

Patients with respiratory failure are often treated with artificial ventilation at elevated pressures. These elevated pressures can damage the lung tissue. It is also uncomfortable for the patients and often requires a high dose of sedative and pain medication. These medications, however, suppress spontaneous respiration and thus increase treatment time.

When a patient is weaned from the ventilator, normally the elevated pressures are reduced gradually by hand. The patient is monitored to be sure that he or she remains stable without this support. SmartCare/PS is integrated into the ventilator and performs this process automatically. After data such as patient weight, type of intubation and other medical data is entered, the breathing rate, tidal volume and end-tidal carbon dioxide parameters of the patient are continuously measured and analyzed by the SmartCare/PS. This data is used as a basis for diagnosis. Depending on this diagnosis, the pressure support is adjusted to the current ventilation needs of the patient. As soon as the pressure support can be reduced to a previously determined threshold, the SmartCare/PS automatically attempts a spontaneous breath. If the patient succeeds in breathing spontaneously, the message „Suggest Separation" is displayed.

After initialization and start, the goal of SmartCare/PS is to wean the patient from the ventilator as quickly as possible.

Special features

SmartCare/PS is not a ventilation mode but a knowledge-based automatic control of the ASB (assisted spontaneous breathing) ventilation mode based on clinically proven protocols.

Innovation

Technical description of the innovation

The knowledge-based SmartCare/PS manages a weaning method frequently used throughout the world. The mode involved is assisted spontaneous breathing (ASB). It is usually used in patients in a hemodynamically stable treatment state for the purpose of weaning them from artificial respiration. For weaning to progress, the parameters (breathing rate, tidal volume, and end-tidal carbon dioxide) need to be constantly monitored, analyzed and handled. The innovation provided by the SmartCare/PS is the collection of the above parameters at 10-second intervals. The data is automatically analyzed every 2 to 5 minutes with respect to the previous adjustment of the pressure support. The SmartCare/PS responds automatically to the analysis by reducing or increasing the pressure support. All diagnoses and values are presented to the physician in a way that suits daily clinic operations -- e.g. display on the monitor.

Innovative content of the solution

In the traditional clinical procedure, various trained personnel analyze discrete blood samples and/or ventilation parameters, possibly taken at various intervals. This approach harbors the error that ventilation support may be adjusted at a time and in a direction that does not or does not sufficiently conform to the current condition of the patient.

SmartCare/PS responds appropriately, adjusting support at the correct time and in the correct direction. Furthermore, it automatically keeps the patient in his or her comfort zone and permits weaning from artificial ventilation as quickly as possible. This gives physicians the opportunity to concentrate on more demanding tasks requiring their expertise.

Improvement of existing solutions

A multicenter study demonstrated that SmartCare/PS, compared to the currently used manual solution, was able to reduce weaning time an average of 4 [2-8] days to 2 [2-6] days (P=0.015), the total ventilation period from 9 [6-15] days to 6 [3-12] days (P=0.020), length of stay (LOS) in the ICU from 17 [9.5-33] days to 12 [6.3-21.8] days (P=0.018) and the reintubation rate from 36% to 19% (P=0.0095).

„A multicenter randomized trial of computer-driven protocolized weaning from mechanical ventilation", FranAois Lellouche, Jordi Mancebo, Philippe Jolliet, Jean Roeseler, Frédérique Schortgen, Michel Dojat, Belen Cabello, Lila Bouadma, Pablo Rodriguez, Salvatore Maggiore, Marc Reynaert, Stefan Mersmann, Laurent Brochard. American Journal of Respiratory Critical Care Medicine (AJRCCM); in print - year of publication 2006.

Qualitative benefit

Rapid weaning reduced the average length of stay in the ICU by up to 33%. In addition, the reintubation rate was slightly reduced. Because length of stay was reduced, the ICU was able to handle more patients. Intensive care units are often bottlenecks in the process flow of the hospital. In particular, often scheduled surgeries cannot be performed because the ICU is not able to accept additional patients. Substantial problems in providing emergency care are being reported from the USA. Emergency admissions frequently will not admit patients because there are no free beds in the ICU for continued treatment. In each case, SmartCare/PS would have a positive effect, since more patients could be routed through the ICU.

The reduced ventilation times also save on medications and other consumables, thus further reducing costs.

Consistent adherence to clinical weaning protocols does create more work, since the ventilator needs constant manual adjustment to patient requirements and a spontaneous breathing attempt must be performed manually at regular intervals. Since the medical weaning protocols are adhered to automatically, regardless of personnel qualifications or workload, the same high quality can be guaranteed during the weaning process without increasing personnel workload.

Cost-benefit analysis

Description

The cost-benefit effects of the SmartCare/PS result from a reduction in weaning time, total ventilation period, length of stay in the ICU as well as reintubation rate.

The shortened length of stay and reduced reintubation rate lead to:

- Reduced personnel costs for physicians, nurses, medico-technical services, and
- Reduced material costs for drugs and equipment.

Costs for the use of the SmartCare/PS were reviewed and the overall effect determined. The projection was based on data from a sample hospital. Using its ratio of ICU beds to total beds, the total number of relevant patients needing respiration was estimated. This is based on the assumption that approx. 20% of all ventilated patients can be treated with SmartCare, which in turn covers 50% of the total ventilation hours.

Cost-benefit effect		SmartCare/PS Procedure
Costs Evita XL with SmartCare*	€	-2990 [p.a. and bed]
number ventilated beds		11000 [ICU beds/year]
Total costs	**Millions €**	**~-32**
Reduction overall ventilation time	€	2000 [~2.6 days]
Reduction in drugs/consumables	€	2000
No. of cases		170000 [p.a.]
Total benefit	**Millions €**	**~680**
Total annual effect	**Millions €**	**~648**

* Assumption: All the ventilated beds must be equipped with the Evita XL with SmartCare (cost of acquisition: € 35,000 per bed; duration of use: 12 years).

The savings potential from a reduction of material and personnel costs totals approx. 648 million euros per year in Germany.

Current projection situation

Mechanical ventilation is a fixed component of the DRG system. In the 2006 catalog, there are over 900 calculated DRGs; the total number of case groups with ventilation times over 95 hours is 54.

Conclusion

Purpose

Many ICU patients must first be artificially ventilated and later weaned from the ventilator at great expense. Weaning is achieved preferably according to consistent guidelines and protocols that specify the gradual reduction in ventilator pressures.

After every manual change in the ventilator parameters, medical personnel must monitor patient stability. This procedure is time-consuming, the risk of treatment errors is relatively high, and improvement is needed.

Innovation

The SmartCare/PS System is a knowledge-based control system that is integrated into the ventilator and allows the patient to be automatically weaned from the ventilator in accordance with a standard protocol. Manual changes to ventilation parameters are no longer necessary. The system independently reduces ventilation pressures and controls the effect on the patient.

Savings effect

Besides reducing personnel workload in the ICU and increasing patient safety, cost savings are realized mainly from the reduction in the average ventilation times by a good two days and possible avoidance of otherwise necessary medications and consumables.

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CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: April 30, 2009

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☑ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		
	Please refer to "Attachment to Form 3454: Certification"	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
Mr Bernd Fabian	President Busniness Unit Critical Care
FIRM/ORGANIZATION Dräger Medical AG & Co. KG, Moislinger Allee 53-55, 23542 Lübeck, Germany	
SIGNATURE	DATE 20.08.07

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Attachment to Form 3454: CERTIFICATION

1) Covered Study:	**„ A Multicenter Randomized Trial of Computer-driven Protocolized Weaning from Mechanical Ventilation"**
Time of Study:	01.09.2002 – 12.06.2003
Time of fin.disc.:	01.09.2002 – 12.06.2004

List of clinical investigators:

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Pablo RODRIGUEZ, Francois LELLOUCHE	Réanimation Médicale, AP-HP, Hopital Henri Mondor, Unité INSERM U 651, Université Paris XII, Créteil;
Michel DOJAT	INSERM/UJF U594, Neuro-imagerie Fonctionelle et Me´tabolique, LRC CEA 30V, CHU de Grenoble, Grenoble, France;
Salvatore MAGGIORE	Istituto di Anestesiologia e Rianimazione–Universita` Cattolica Policlinico A.Gemelli, Rome, Italy;

2) Covered Study:	**„ Daily Practice With SmartCare in a Difficult to Wean Patient"**
Time of Study:	04.2005 – 04.2006
Time of fin.disc.:	04.2005 – 04.2007

List of clinical investigators:

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Lübeck, 20.08.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: April 30, 2009

TO BE COMPLETED BY APPLICANT

The following information concerning Please ref. to "Attachment to Form 3455: Disclosure (*Name of clinical investigator*), who participated as a clinical investigator in the submitted study A Multicenter Randomized Trial of Computer-driven Protocolized Weaning from Mechanical Ventilation (*Name of clinical study*) is submitted in accordance with 21 CFR part 54. The named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:

Please mark the applicable check boxes.

- ☐ any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;
- ☑ any significant payments of other sorts made on or after February 2, 1999 from the sponsor of the covered study such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;
- ☐ any proprietary interest in the product tested in the covered study held by the clinical investigator;
- ☐ any significant equity interest as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

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Attachment to Form 3455: DISCLOSURE

Covered Study: **„A Multicenter Randomized Trial of Computer-driven Protocolized Weaning from Mechanical Ventilation"**

Time of Study: 01.09.2002 – 12.06.2003
Time of fin.disc.: 01.09.2002 – 12.06.2004

List of clinical investigators:

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Financial Agreement:	Employee of Dräger Medical
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Financial Agreement:	325€ per included patient (34 patients) = 11050€ 15.000€ p.y. for 2001-2004 for ongoing research paid to the Organisation: Naturalia et Biologia, 46 Boulevard des Invalides, 75007 Paris, France
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Financial Agreement:	320€ per included patient (40patients) = 12.800€
Philippe JOLLIET	Soins Intensifs de Me´decine, Ho^pital Cantonal Universitaire, Geneva, Switzerland;
Financial Agreement:	1700€ travel to congresses 320€ per included patient (18 patients) = 5760€
Belen CABELLO	Servei Medicina Intensiva, Hospital Sant Pau, Barcelona, Spain
Financial Agreement:	300€ for English/Spanish Translation work

Lübeck,

.....

Bernd Fabian
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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Charles M. Kerns

Subject: 510(k) Number K073412 / S

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

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Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			✓
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Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Is clinical data necessary to support the review of this 510(k)?		✓	
Does this device include an Animal Tissue Source?			✓
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number	Class*	Product Code
21 CFR 868.5895	II	CBK

(*If unclassified, see 510(k) Staff).

Additional Product Codes: _____

Review: [signature] (Branch Chief) ARDB (Branch Code) 2/5/08 (Date)

Final Review: [signature] (Division Director) 2/5/08 (Date)

Rev. 5/30/07

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K072412/S002

Date: February 4, 2008
To: The Record
From: Charles M. Kerns, Regulatory Reviewer

Office: HFZ-480
Division: DAGID/ARDB

510(k) Holder: Dräger Medical AG & Co. KG
Device Name: EvitaXL with SmartCare Option
Contact: Kathy Anderson
Phone: 215-660-2078
Fax: 215-721-5424
Email: Kathy.anderson@draegermed.com

A. Purpose and Submission Summary

The 510(k) holder would like to add promotional claims to the EvitaXL with SmartCare Option. Literature and proposed device labeling was provided in support of the additional claims.

B. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form		X	

C. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?	X		
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

The EvitaXL with SmartCare Option is a continuous ventilation system. The system is already

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cleared under K051263. (b)(4) Trade Secret Process - Product Specs [redacted]

D. Indications for Use

The indications for use (IFU) is provided in the submission in Section 4. The IFU states:

"The EvitaXL is a long-term ventilator for intensive care for adults, children, and infants with a body weight of at least 3 kg (6.6 lbs).

With SmartCare™/PS the EvitaXL is intended to stabilize the patient's spontaneous breathing in a "comfortable zone" and to reduce inspiratory support for adults and children with a body weight of at least 15 kg (33 lbs.). The patients should be haemodynamically stable with adequate oxygenation and spontaneous breathing. SmartCare can be used for intubated or tracheotomized patients. Patients with body weight between 15 and 35 kg (33.1 and 77.8 lbs) must be endotracheally intubated and ventilated with active humidification.

SmartCare™/PS is contraindicated in case of sever COPD and sever neurologic disorder that affects the cerebral control mechanism of the spontaneous breathing pattern."

E. Predicate Device Comparison

The predicate device cited for comparison is:

K051263 – EvitaXL with SmartCare Option, Dräger Medical AG & Co. KG

(b)(4) Trade Secret Process - Product Specs [redacted]

F. Labeling

(b)(4) Trade Secret Process - Product Specs [redacted]

G. Sterilization/Shelf Life/Reuse

The device is not sterile. Since no changes are being made to the already cleared device, this section was not applicable in this submission.

H. Biocompatibility

Since no changes are being made to the already cleared device, this section was not applicable in this submission.

I. Software

Since no changes are being made to the already cleared device, this section was not applicable in this submission. None of the information in the following table was provided or necessary for review.

Version:		
Level of Concern:		
	Yes	No
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies: None detected		

J. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Since no changes are being made to the already cleared device, this section was not applicable in this submission.

K. Performance Testing – Bench

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

L. Performance Testing – Animal

No animal testing was conducted or is required for this submission.

M. Performance Testing – Clinical

No animal testing was conducted or is required for this submission.

N. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: SE

Note: See Premarket Notification 510(k) Flowchart Decision Tree for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:

The review of the literature is necessary to evaluate the basis for the additional promotional claims.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

(b)(4) Trade Secret Process - Product Specs [redacted]

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

(b)(4) Trade Secret Process - Product Specs [redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

P. Contact History

(b)(4) Trade Secret Process - Product Specs

[redacted]

Q. Recommendation

I recommend this file be considered substantially equivalent to the cited predicate device.

Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK

Charles M. Kerns, Reviewer — Date: 2/4/08

Michael Husband, Branch Chief — Date: 2/5/08

Kerns, Charles

om: Shure, Deborah*
ent: Sunday, February 03, 2008 2:30 PM
To: Kerns, Charles
Cc: Husband, Michael J
Subject: Drager K072412-S002

Chuck,

(b)(4) Trade Secret Process - Product Specs

[redacted]

Deborah

Deborah Shure, MD
1851 SW 13th Street
Miami, FL 33145
Email: deborah.shure@fda.hhs.gov
Voice: 305-541-0071
Fax: 305-541-0027
Cell: 305-815-2613

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Charles M. Kerous

Subject: 510(k) Number K072412/S1

To: The Record

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☑ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Does this device include an Animal Tissue Source?			
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: [signature] (Branch Chief) ARDB (Branch Code) 12/3/07 (Date)

Final Review: _____ (Division Director) (Date)

Rev. 5/30/07

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K072412/S001

Date: December 31, 2007
To: The Record
From: Charles M. Kerns, Regulatory Reviewer

Office: HFZ-480
Division: DAGID/ARDB

510(k) Holder: Dräger Medical AG & Co. KG
Device Name: EvitaXL with SmartCare Option
Contact: Kathy Anderson
Phone: 215-660-2078
Fax: 215-721-5424
Email: Kathy.anderson@draegermed.com

A. Purpose and Submission Summary

The 510(k) holder would like to add promotional claims to the EvitaXL with SmartCare Option. Literature and proposed device labeling was provided in support of the additional claims.

B. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form		X	

C. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?	X		
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

The EvitaXL with SmartCare Option is a continuous ventilation system. The system is already

cleared under K051263. (b)(4) Trade Secret Process - Product Specs [redacted].

D. Indications for Use

The indications for use (IFU) is provided in the submission in Section 4. The IFU states:

"The EvitaXL is a long-term ventilator for intensive care for adults, children, and infants with a body weight of at least 3 kg (6.6 lbs).

With SmartCare™/PS the EvitaXL is intended to stabilize the patient's spontaneous breathing in a "comfortable zone" and to reduce inspiratory support for adults and children with a body weight of at least 15 kg (33 lbs.). The patients should be haemodynamically stable with adequate oxygenation and spontaneous breathing. SmartCare can be used for intubated or tracheotomized patients. Patients with body weight between 15 and 35 kg (33.1 and 77.8 lbs) must be endotracheally intubated and ventilated with active humidification.

SmartCare™/PS is contraindicated in case of sever COPD and sever neurologic disorder that affects the cerebral control mechanism of the spontaneous breathing pattern."

E. Predicate Device Comparison

The predicate device cited for comparison is:

K051263 – EvitaXL with SmartCare Option, Dräger Medical AG & Co. KG

(b)(4) Trade Secret Process - Product Specs

[redacted]

F. Labeling

(b)(4) Trade Secret Process - Product Specs

[redacted]

G. Sterilization/Shelf Life/Reuse

The device is not sterile. Since no changes are being made to the already cleared device, this section was not applicable in this submission.

H. Biocompatibility

Since no changes are being made to the already cleared device, this section was not applicable in this submission.

I. Software

Since no changes are being made to the already cleared device, this section was not applicable in this submission. None of the information in the following table was provided or necessary for review.

Version:		
Level of Concern:		
	Yes	**No**
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies: None detected		

J. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Since no changes are being made to the already cleared device, this section was not applicable in this submission.

K. Performance Testing – Bench

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

L. Performance Testing – Animal

No animal testing was conducted or is required for this submission.

M. Performance Testing – Clinical

No animal testing was conducted or is required for this submission.

N. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See Premarket Notification 510(k) Flowchart Decision Tree for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

   The review of the data is necessary to evaluate the basis for the additional promotional claims.

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

   (b)(4) Trade Secret Process - Product Specs [redacted].

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

P. Contact History

[redacted] (b)(4) Trade

Q. Recommendation

I recommend this file be placed on hold until the requested additional information is submitted for review.

Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK

Charles M. Kerns, Reviewer — Date: 12/31/07

Michael Husband, Branch Chief — Date: 12/31/07

OFFICE OF DEVICE EVALUATION
510K Clinical Review of Request for Additonal Information Response

From: Deborah Shure, MD
ODE/DAGID/ARDB

To: Charles Kerns
ODE/DAGID/ARDB

CC: Michael Husband

Subject: **K072412 Supplement 1**
Device: Option SmartCare/PS for the EvitaXL ventilator
Sponsor: Dräger Medical AG & Co

Date: Submission received December 10, 2007 in response to FDA request for additional information dated October 15, 2007

SUMMARY AND RECOMMENDATION

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Charles M. Kerns

Subject: 510(k) Number K072412

To: The Record

Please list CTS decision code AF

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ Screening Checklist)

☑ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABBREVIATED STANDARDS DATA FORM.DOC)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)?			
Does this device include an Animal Tissue Source?			
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: for MJH ARDB 10/12/07

(Branch Chief) (Branch Code) (Date)

Final Review:

(Division Director) (Date)

Rev. 5/30/07

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		**YES**	**NO**
1. Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)			
2. Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?			
3. Does this device type require a PMA by regulation? (Please see management.)			
Questions 4-8 are intended to help you start your review:		**YES**	**NO**
4. Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)			
5. a. Did the firm request expedited review? (See management.)			
b. Was expedited review granted? (See *Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions*, http://www.fda.gov/cdrh/mdufma/guidance/108.html)			
6. To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:		
7. To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:		
8. Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see *Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission* http://www.fda.gov/cdrh/mdufma/guidance/1215.html)			

Rev. 5/30/07

DEPARTMENT OF HEALTH AND HUMAN SERVICES MEMORANDUM

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K072412

Date: October 11, 2007
To: The Record
From: Charles M. Kerns, Regulatory Reviewer

Office: HFZ-480
Division: DAGID/ARDB

510(k) Holder: Dräger Medical AG & Co. KG
Device Name: EvitaXL with SmartCare Option
Contact: Kathy Anderson
Phone: 215-660-2078
Fax: 215-721-5424
Email: Kathy.anderson@draegermed.com

A. Purpose and Submission Summary

The 510(k) holder would like to add promotional claims to the EvitaXL with SmartCare Option. Literature and proposed device labeling was provided in support of the additional claims.

B. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form		X	

C. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?	X		
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?	X		
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	X		

The EvitaXL with SmartCare Option is a continuous ventilation system. The system is already

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cleared under K051263. (b)(4) Trade Secret Process - Product Specs [redacted].

D. Indications for Use

The indications for use (IFU) is provided in the submission in Section 4. The IFU states:

"The EvitaXL is a long-term ventilator for intensive care for adults, children, and infants with a body weight of at least 3 kg (6.6 lbs).

With SmartCare™/PS the EvitaXL is intended to stabilize the patient's spontaneous breathing in a "comfortable zone" and to reduce inspiratory support for adults and children with a body weight of at least 15 kg (33 lbs.). The patients should be haemodynamically stable with adequate oxygenation and spontaneous breathing. SmartCare can be used for intubated or tracheotomized patients. Patients with body weight between 15 and 35 kg (33.1 and 77.8 lbs) must be endotracheally intubated and ventilated with active humidification.

SmartCare™/PS is contraindicated in case of sever COPD and sever neurologic disorder that affects the cerebral control mechanism of the spontaneous breathing pattern."

E. Predicate Device Comparison

The predicate device cited for comparison is:

K051263 – EvitaXL with SmartCare Option, Dräger Medical AG & Co. KG

(b)(4) Trade Secret Process - Product Specs

[redacted]

F. Labeling

(b)(4) Trade Secret Process - Product Specs

[redacted]

G. Sterilization/Shelf Life/Reuse

The device is not sterile. Since no changes are being made to the already cleared device, this section was not applicable in this submission.

H. Biocompatibility

Since no changes are being made to the already cleared device, this section was not applicable in this submission.

I. Software

Since no changes are being made to the already cleared device, this section was not applicable in this submission. None of the information in the following table was provided or necessary for review.

Version:		
Level of Concern:		
	Yes	No
Software description:		
Device Hazard Analysis:		
Software Requirements Specifications:		
Architecture Design Chart:		
Design Specifications:		
Traceability Analysis/Matrix:		
Development:		
Verification & Validation Testing:		
Revision level history:		
Unresolved anomalies: None detected		

J. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Since no changes are being made to the already cleared device, this section was not applicable in this submission.

K. Performance Testing – Bench

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

L. Performance Testing – Animal

No animal testing was conducted or is required for this submission.

M. Performance Testing – Clinical

No animal testing was conducted or is required for this submission.

N. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	X		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	X		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	X		If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

Note: See Premarket Notification 510(k) Flowchart Decision Tree for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

(b)(4) Trade Secret Process - Product Specs

6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7. Explain why existing scientific methods can not be used:

8. Explain what performance data is needed:

(b)(4) Trade Secret Process - Product Specs

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

(b)(4) Trade Secret Process - Product Specs

(b)(4) Trade Secret Process - Product Specs

[redacted]

P. Contact History

(b)(4) Trade Secret Process - Product Specs [redacted]

Q. Recommendation

I recommend this file be placed on hold until the requested additional information is submitted for review.

Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK

Charles M. Kerns, Reviewer — Date: 10/11/07

Michael Husband, Branch Chief — Date: 10/12/07

OFFICE OF DEVICE EVALUATION
CLINICAL REVIEW

From: Deborah Shure, MD
ODE/DGRND/GSDB

To: Charles Kerns, RN, BSN, MS, CDR USPHS
ODE/DAGID/ARDB

CC: Michael Husband
Ginette Michaud, MD, Deputy Division Director

Subject: **K072412**
Device: Option SmartCare/PS for the EvitaXL ventilator
Sponsor: Dräger Medical AG & Co. KG

Date: Submission dated August 23, 2007, received FDA CDRH August 27, 2007

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

**Please send this to the 510k Staff in Word. You do not need anyone to sign this in person.

Form for Converting a Special 510(k) to a Traditional or Abbreviated 510(k)

Date: _____September 11, 2007_____

Reviewer: _____Melanie Choe_____

510(k) Number: ___K072412_____

Device Name: Option SmartCare for EvitaXL, SmartCare kit Capno package, CO2 sensor CapnoSmart

Reason for Conversion: (if this is a change in indications for use, please list the old indication and the new indication)

(b)(4) Trade Secret Process - Product Specs

[redacted]

Division Director Concurrence/Name: (Please get this before calling or e-mailing POS)

____Chiu Lin_____

Date of POS Concurrence (please document POS contact):

_____September 11, 2007___Marjorie Shulman_____

Date of Phone Conversation: _____September 6, 2007 with Kathy Anderson_____

*****Please add this to the file**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 10, 2007

DRAGER MEDICAL AG & CO. KGAA
C/O DRAGER MEDICAL , INC.
3135 QUARRY ROAD
TELFORD, PA 18969
ATTN: KATHY ANDERSON

510(k) Number: K072412
Product: OPTION SMARTCARE FOR EVITAXL,SMARTCAR E KIT CAPNO

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K072412/S1

Dräger medical

A Dräger and Siemens Company

FDA/CDRH/ODE/PMO

2007 DEC 10 A 10: 05

RECEIVED

Dräger Medical AG & Co. KG, Moislinger Allee 53-55, 23542 Lübeck, Germany

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
Attn. Ms. / Mr. Chiu Lin
9200 Corporate Boulevard
Rockville, Maryland 20850
USA

Date
2007-12-06
Our ref.
mt-pq-ra
Phone
+49 (0) 451 882 2041
Fax
+49 (0) 451 882 4351
E mail
gustav.paulsen@draeger.com

Special 510(k) Premarket Notification Option SmartCare / PS for the EvitaXL (K072412)
Additional Information

Dear Ms. / Mr. Chiu Lin,

In response to your request for additional information dated October 15, 2007 for Option SmartCare / PS for the EvitaXL ventilator, please find attached the information requested.

Please find enclosed two (2) paper copies of additional information.

If there is a need to discuss any aspect of this Premarket Notification, please contact either the undersigned at +49 (451) 882-5367, or the assigned United States agent Ms. Kathy Anderson, Dräger Medical System, Inc., at (215) 660-2078.

With best regards,

Gustav Paulsen
Manager Regulatory Affairs

Dr. Karin Lübbers
Senior Manager Regulatory Affairs

Enclosure: Two paper copies submitted,
Attachment: CDRH Submission Cover Sheet

K1

93

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
5/12/2007		K072412

CTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Dräger Medical AG & Co. KG	Establishment Registration Number *(if known)* 9611500		
Division Name *(if applicable)* N/A	Phone Number *(including area code)* (+49) 451-882-5367		
,et Address Moislinger Allee 53-55	FAX Number *(including area code)* (+49) 451-882-4351		
City Luebeck	State / Province N/A	ZIP/Postal Code D-23542	Country Germany
Contact Name Dr. Karin Luebbers			
Contact Title Senior Manager, Regulatory Affairs	Contact E-mail Address karin.luebbers@draeger.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name Draeger Medical Systems, Inc.			
Division Name *(if applicable)* N/A	Phone Number *(including area code)* (215) 660-2078		
Street Address 3135 Quarry Rd.	FAX Number *(including area code)* (215) 721-5424		
City Telford	State / Province PA	ZIP/Postal Code 18969	Country U.S.A.
Contact Name Kathy Anderson			
'act Title ,ior Director, Regulatory Affairs	Contact E-mail Address kathy.anderson@draeger.com		

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	CBK	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached
☐ 510 (k) statement

ormation on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K051263	1	EvitaXL with Option SmartCare	1	Dräger Medical AG & Co. KG
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device		Model Number
1	Option SmartCare for EvitaXL	1	84 15 941
2	SmartCare kit Capno package	2	84 15 942
3	CO2 sensor CapnoSmart	3	68 71 500
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code
CBK

C.F.R. Section *(if applicable)*
868.5895

Device Class
☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Classification Panel
Anesthesiology

Indications *(from labeling)*
please see Section 4 of the 510(k) submission

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number 9611500	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name Dräger Medical AG & Co. KG		Establishment Registration Number 9611500		
Division Name *(if applicable)* N/A		Phone Number *(including area code)* (+49) 451-882-5357		
Street Address Moislinger Allee 53-55		FAX Number *(including area code)* (+49) 451-882-4351		
City Luebeck		State / Province N/A	ZIP/Postal Code D-23542	Country Germany
Contact Name Dr. Karin Luebbers	Contact Title Senior Manager, Regulatory Affairs		Contact E-mail Address karin.luebbers@draeger.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
.et Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

gency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Drägermedical
A Dräger and Siemens Company

Dräger Medical AG & Co. KG, Moislinger Allee 53-55, 23542 Lübeck, Germany

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
Attn. Ms. / Mr. Chiu Lin
9200 Corporate Boulevard
Rockville, Maryland 20850
USA

FDA CDRH DMC
DEC 10 2007
Received

Date
2007-12-06
Our ref.
mt-pq-ra
Phone
+49 (0) 451 882 2041
Fax
+49 (0) 451 882 4351
E mail
gustav.paulsen@draeger.com

Special 510(k) Premarket Notification Option SmartCare / PS for the EvitaXL (K072412)
Additional Information

Dear Ms. / Mr. Chiu Lin,

In response to your request for additional information dated October 15, 2007 for Option SmartCare / PS for the EvitaXL ventilator, please find attached the information requested.

Please find enclosed two (2) paper copies of additional information.

If there is a need to discuss any aspect of this Premarket Notification, please contact either the undersigned at +49 (451) 882-5367, or the assigned United States agent Ms. Kathy Anderson, Dräger Medical System, Inc., at (215) 660-2078.

With best regards,

Gustav Paulsen
Manager Regulatory Affairs

Dr. Karin Lübbers
Senior Manager Regulatory Affairs

Enclosure: Two paper copies submitted,
Attachment: CDRH Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
5/12/2007		K072412

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
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☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Dräger Medical AG & Co. KG	Establishment Registration Number *(if known)* 9611500		
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Street Address Moislinger Allee 53-55	FAX Number *(including area code)* (+49) 451-882-4351		
City Luebeck	State / Province N/A	ZIP/Postal Code D-23542	Country Germany
Contact Name Dr. Karin Luebbers			
Contact Title Senior Manager, Regulatory Affairs	Contact E-mail Address karin.luebbers@draeger.com		

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Company / Institution Name Draeger Medical Systems, Inc.			
Division Name *(if applicable)* N/A	Phone Number *(including area code)* (215) 660-2078		
Street Address 3135 Quarry Rd.	FAX Number *(including area code)* (215) 721-5424		
City Telford	State / Province PA	ZIP/Postal Code 18969	Country U.S.A.
Contact Name Kathy Anderson			
Contact Title Senior Director, Regulatory Affairs	Contact E-mail Address kathy.anderson@draeger.com		

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	CBK	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☐ 510 (k) summary attached
- ☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K051263	1	EvitaXL with Option SmartCare	1	Dräger Medical AG & Co. KG
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device		Model Number
	Option SmartCare for EvitaXL	1	84 15 941
2	SmartCare kit Capno package	2	84 15 942
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4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
CBK	868.5895	☐ Class I ☒ Class II
Classification Panel: Anesthesiology		☐ Class III ☐ Unclassified

Indications *(from labeling)*

please see Section 4 of the 510(k) submission

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number 9611500	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name Dräger Medical AG & Co. KG		Establishment Registration Number 9611500		
Division Name *(if applicable)* N/A		Phone Number *(including area code)* (+49) 451-882-5357		
Street Address Moislinger Allee 53-55		FAX Number *(including area code)* (+49) 451-882-4351		
City Luebeck		State / Province N/A	ZIP/Postal Code D-23542	Country Germany
Contact Name Dr. Karin Luebbers	Contact Title Senior Manager, Regulatory Affairs		Contact E-mail Address karin.luebbers@draeger.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
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Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
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City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

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	Standards No.	Standards Organization	Standards Title	Version	Date
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6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Additional Information

for the

Option SmartCare / PS for the EvitaXL ventilator

510(k) Premarket Notification (K072412)
Requested on October 15, 2007

001

(b)(4) Trade Secret Process - Product Specs

[redacted]

002

(b)(4) Trade Secret Process - Product Specs

[redacted]

003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2007

Dräger Medical AG & Co. KG
C/O Kathy Anderson
Senior Director Regulatory Affairs
Drager Medical, Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K072412
Option SmartCare/PS for the EvitaXL ventilator
Dated: August 23, 2007
Received: August 27, 2007

Dear Ms. Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the following information:

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete..

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Charles M. Kerns at 240-276-3775. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

For

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

(b)(4) Trade Secret Process - Product Specs

[redacted]

008

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

November 06, 2007

DRAGER MEDICAL AG & CO. KGAA
C/O DRAGER MEDICAL , INC.
3135 QUARRY ROAD
TELFORD, PA 18969
ATTN: KATHY ANDERSON

510(k) Number: K072412
Device: OPTION SMARTCARE FOR EVITAXL,SMARTCAR E KIT CAPNO

Extended Until: 12-DEC-2007

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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RECEIVED NOV 0 8 2007

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(b)(4) Trade Secret Process - Product Specs

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Performance and Testing Data (revised Section 7)

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011

(b)(4) Trade Secret Process - Testing

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(b)(4) Trade Secret Process - Testing

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Proposed Device Labeling (revised Section 6)

The device labeling of the EvitaXL and the SmartCare Option in terms of instructions for use and device label (adhesives) is not changed. Thus the material is not included in this submission.

The promotional material included in the first SmartCare submission K#051263 remains in use unchanged and is not included in this submission.

The changes covered by this submission refer only to the promotional material appended to this section. It comprises customer presentations, a print advertisement and an Excel spreadsheet called 'Hospital Flow Calculation Tool'.

Dräger Medical intends to create more promotional material based on the claims stated in this submission.

Summary of Claims

The claims made in the promotional material are summarized as follows:

(b)(4) Trade Secret Process - Product Specs

[redacted]

Cost reduction:

- Impact the bottom line

All claims include the following statement:
"Results are based on a European Multicenter Randomized Trial with 144 patients demonstrating improved respiratory condition, with stable hemodynamic and neurologic status, and no ARDS."

The concrete presentation of the claims is shown in the appended slides

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List of Appendices

Appendix 6.1:	Excerpt form Presentation "Impact"
Appendix 6.2:	Excerpt form Presentation "Integrated CareArea™ Solutions for Critical Care"
Appendix 6.3:	Excerpt form Presentation "Impact Solutions for Critical Care Ventilation"
	NOTE: The complete presentations listed under 8.1 - 8.3 cover a wide range of Dräger products. The excerpts included here comprise the SmartCare section of these presentations.
Appendix 6.4:	"Impact" Print Ad
Appendix 6.5:	Presentation: Hospital Flow Calculation Tool (including screen shots)
Appendix 6.6:	Paper: "The Hospital Flow Diagnostic" Description for Excel based Calculation Tool
Appendix 6.7:	CD Rom with Hospital Flow Calculation Tool Contents: • Throughput_Simulation US 1.3 .xls (MS Excel Spreadsheet) • qtp.exe (QTP 4.0, required Excel PlugIn)

Hospital Flow Calculation Tool

The calculation tool uses queuing theory to model patient throughput through a hospital or a single unit based upon admission requests, available beds and length of stay on the ICU.

The tool has neither diagnostic nor therapeutic inputs or outputs.

As potential ICU patients cannot wait for treatment, the allowed queue is zero. The simulation calculates the probability of the ICU being full and therefore the probability that patients that cannot be admitted due to full occupancy of the ICU have to be diverted to other hospitals.

Input parameters for the simulation are:

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The actual hospital data are modified allowing for the outcome effects of e.g. SmartCare/PS. The reduced length of stay results in an increased throughput for the ICU. This is shown by the main output parameters of the simulation:

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These data are transferred into a business case calculation considering the coverage of fix costs of a day at the ICU and the revenues of additionally treated patients. The impact on the financial result of the hospital is shown as the final result of the calculation.

NOTE:

For reviewing the tool please refer to the appended CD ROM. Install QTP (a package of Excel formulas for modeling queues) first. Open 'Throughput_Simulation US 1.3 .xls'

NOTE:

Changes made to the promotional material due to FDA's deficiencies correction are labeled as follows: text portions that were removed are crossed out, their new substitutes are underlined.

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031

~~Accelerate healing~~ Improve therapy
The challenge

Drägermedical
A Dräger and Siemens Company

- **Cost pressure**
  - **Mechanical ventilation is associated with significantly higher daily costs for patients receiving treatment in the ICU unit throughout their entire ICU stay (mean ICU cost for mechanically ventilated patients: $ 31,574 +/- 42,570 and for those not mechanically ventilated: $12,931 +/- 20,569) [12]**
- **Overcrowded care units**
  - **"Critically ill patients have been reported to wait extraordinarily long periods of time in the ED until an inpatient critical care bed is available" [13]**

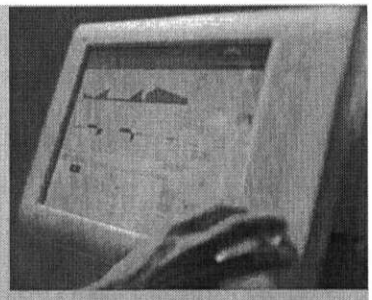
Reference: [12] Dasta JF et al.; Crit Care Med. 2005 Jun;33(6):1434-5.
[13] S Trzeciak and E P Rivers; Emerg. Med. J. 2003; 20; 402-405

~~Accelerate healing~~ Improve therapy
The solution

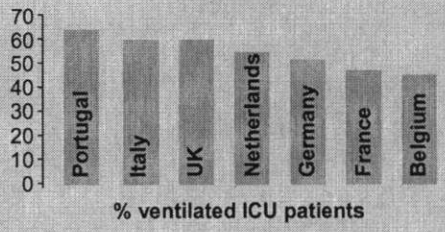
Drägermedical
A Dräger and Siemens Company

Acute Phase | Weaning Phase | Recovery Phase

- **Reduce weaning duration to impact length of stay in the ICU**
  - **Integrate protocolized care by using our state-of-the-art ventilator – the EvitaXL with SmartCare™/PS, a knowledge- based weaning option, which has clear advantages over non-automated weaning protocols**



42% of ventilation time in hospitals is used for weaning



Emergency Care · Perioperative Care · Critical Care · Perinatal Care · Home Care

Because you care

033

~~Accelerate healing~~ Improve therapy
The impact

Dräger medical
A Dräger and Siemens Company

Acute Phase | Weaning Phase | Recovery Phase

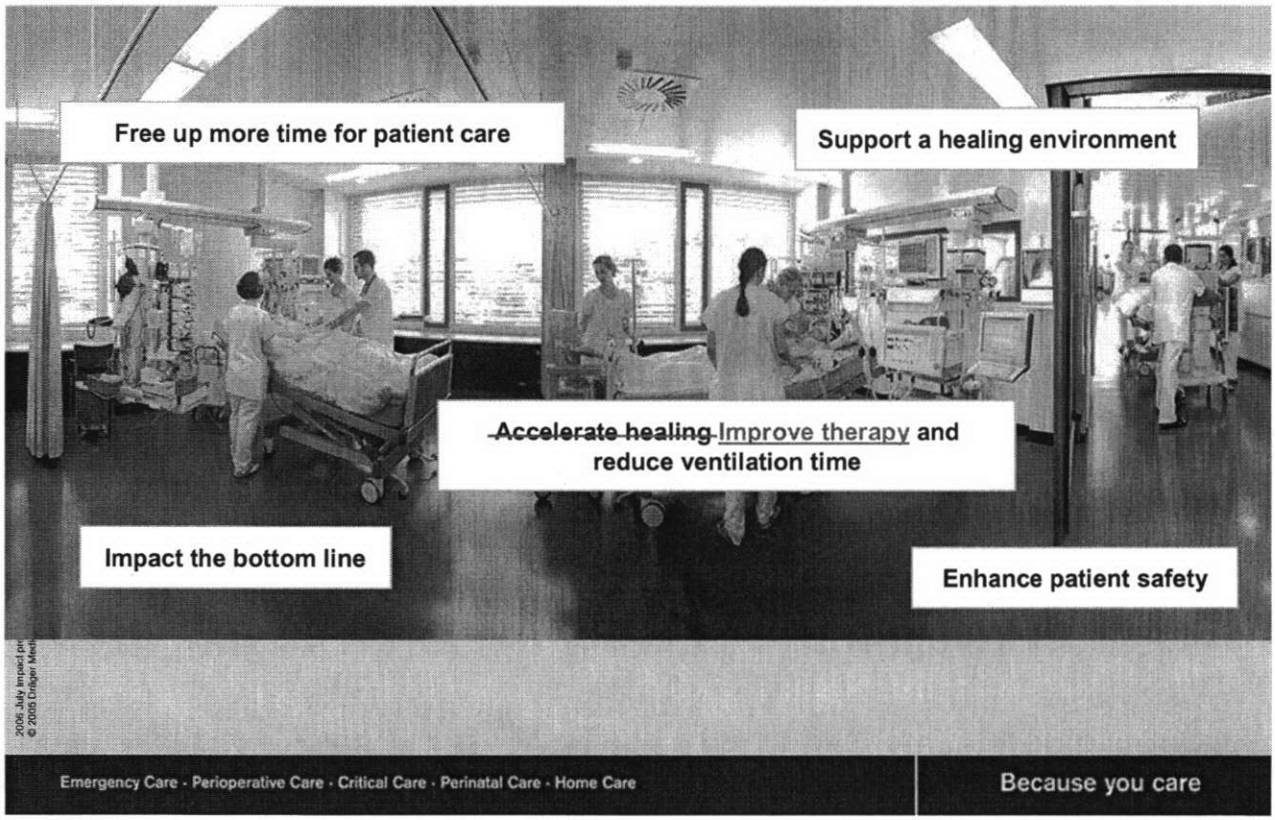
- **A multicenter trial proved that compared to non-automated weaning protocols SmartCare:** [14, 15] 1)
  - **Reduces overall ventilation time by up to 33%**
  - **Decreases ICU length of stay by up to ~~29%~~ 20%**
  - **Reduces weaning duration by up to ~~50%~~ 40%**
  - **Supports 100% weaning protocol compliance**

1) Results are based on a European Multicenter Randomized Trial with 144 patients demonstrating improved respiratory condition, with stable hemodynamic and neurologic status, and no ARDS.

Reference: [14] F Lellouche et al, ~~Intensive Care Medicine 2004~~ Am J Respir Crit Care Med Vol 174, pp 894-900, 2006
[15] M Dojat et al; Art Intell Med 1997

Impact your entire Critical Care process

Drägermedical
A Dräger and Siemens Company



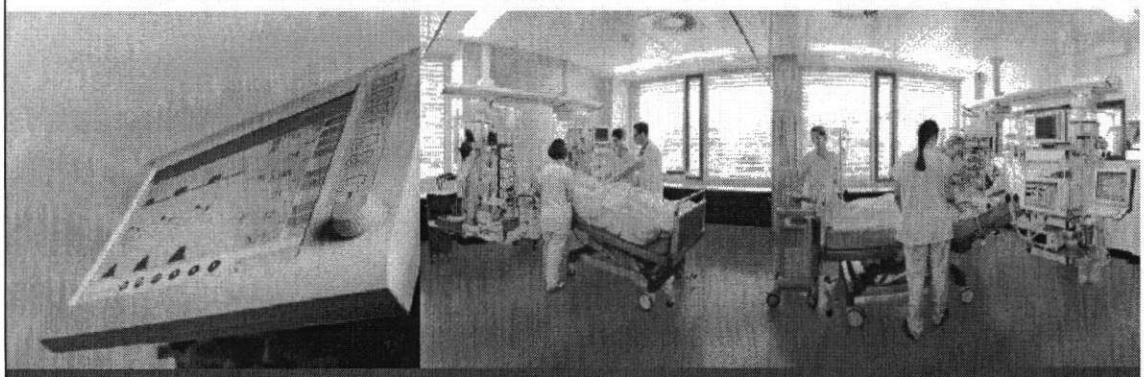
Emergency Care · Perioperative Care · Critical Care · Perinatal Care · Home Care | Because you care

035

Appendix 6.4: "Impact" Print Ad

Dräger

What's one way to dramatically impact Critical Care?



Reduce overall ventilation time by up to **33%***

with Dräger Medical's SmartCare™ automated weaning. It's not only possible... it's documented. Think of what that can mean to your patients... your productivity... and your bottom line. Yet it's just one aspect of our integrated CareArea™ Solutions for Critical Care... and the entire care process. To discover how all of our innovative solutions can impact your care process, visit www.draeger.com.

*E. Lellouche et al., Intensive Care Medicine 2004, Vol. 30, Supplement 1, 234-P69.
Am J Respir Crit Care Med Vol 174. pp 894-900, 2006

Results are based on a European Multicenter Randomized Trial with 144 patients demonstrating improved respiratory conditions, with stable hemodynamic and neurologic status, and no ARDS.

100 Years of Innovation in Ventilation.
Dräger. Technology for Life®

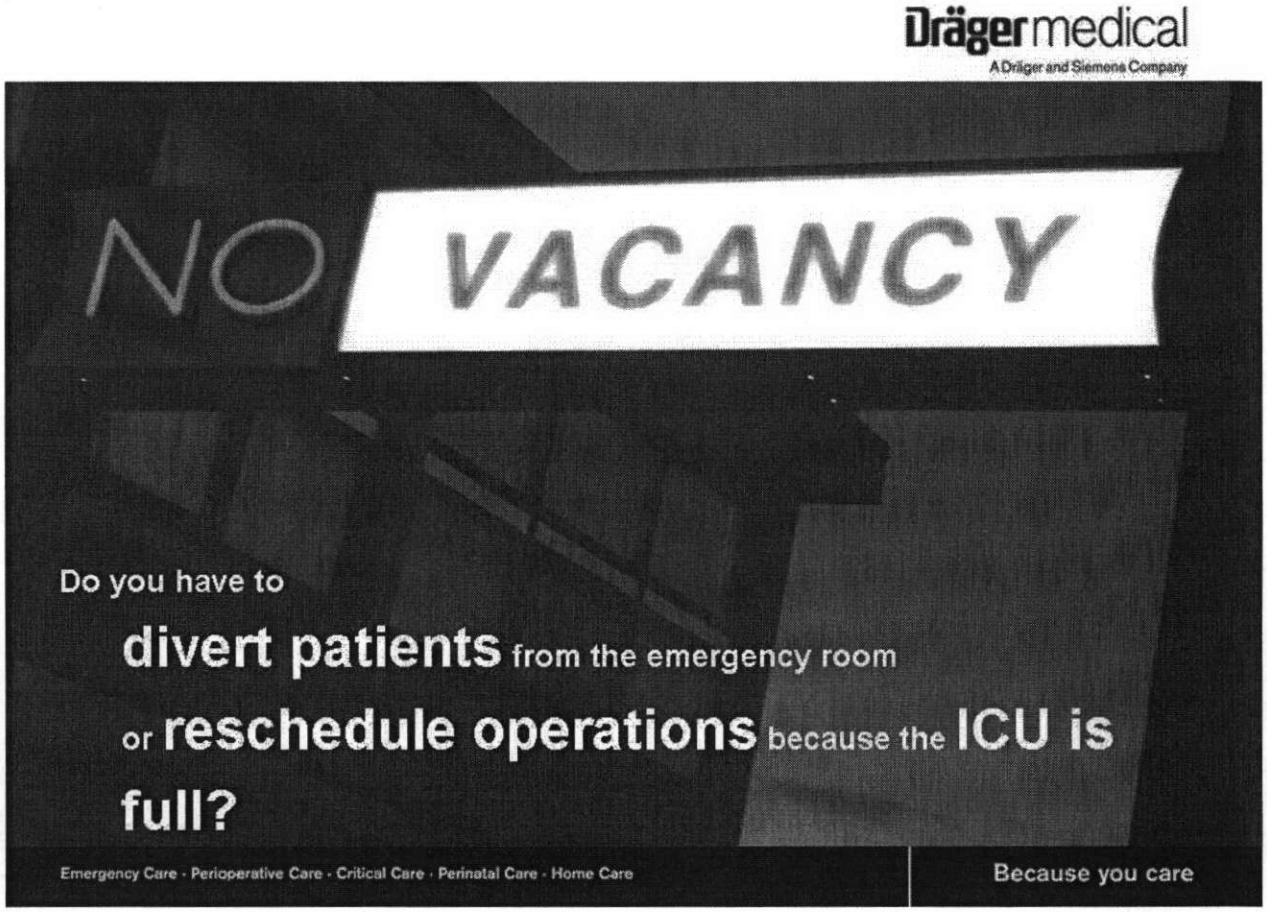
Dräger Medical: Emergency Care > Perioperative Care > Critical Care > Perinatal Care > Home Care

036

Appendix 6.5: Hospital Throughput Calculation Tool

The presentation contained in this appendix gives an overview on the calculation of ICU throughput with the Excel spreadsheet.

Pages that contain screenshots from the spreadsheet are marked with ***)XLS**.



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2.4

The Leapfrog Group's Patient Safety Practices, 2003:

The Potential Benefits of Universal Adoption

Research Director
John D. Birkmeyer, MD
Professor of Surgery
University of Michigan

Project Manager
Justin B. Dimick, MD
Research Fellow
Dartmouth Medical School

February 2004

THE **LEAPFROG** GROUP
for **Patient Safety**
Rewarding **Higher Standards**

Table of Contents

EXECUTIVE SUMMARY

The Leapfrog Group is a large coalition of more than 150 private and public sector health care purchasers working together to improve the quality of healthcare. The Leapfrog Group's quality improvement efforts highlight three main areas: 1) computer physician order entry (CPOE); 2) evidence-based hospital referral (EHR) for high-risk surgery and neonatal intensive care; and 3) ICU physician staffing (IPS).

The following report estimates the benefits that could potentially be achieved if every non-rural hospital in the United States complied fully with the 2003 Leapfrog safety standards. As in our previous analysis for the 2000 standards, we approached the analysis in two steps. First, we estimated the population at risk—the number of patients in metropolitan areas who are currently receiving care in hospitals not meeting the Leapfrog standards. Second, we estimated baseline risks in hospitalized patients, and the potential risk reductions associated with each of the safety standards. Our estimates have been updated from our previous analysis to account for both changes in the Leapfrog safety specifications and new scientific evidence since our last report.

The following Table summarizes the results of our baseline analysis:

Leapfrog Safety Initiative	Potential benefit with full implementation
Computerized Physician Order Entry	567,000 serious medication errors avoided
Evidence-Based Hospital Referral	
Five high-risk procedures	7,602 lives saved
High-risk deliveries	3,606 lives saved
ICU Physician Staffing	54,133 lives saved

Although our analysis is based on the best information currently available, there remain gaps in existing scientific knowledge. In particular, there was insufficient research to allow us to estimate the amount of morbidity (injury or disability) associated with errors in treatment, surgery, or medications. Also, as outlined later in our report, universal adoption of each standard faces several implementation challenges and would have other indirect policy implications. Nonetheless, we believe that successful adoption of The Leapfrog Group's three safety initiatives would significantly reduce the large annual toll of avoidable deaths and improve patient safety in hospitals across the United States.

Computer physician order entry

The Leapfrog Group's standard for computer physician order entry (CPOE) requires that hospitals use a computer system that includes prescribing-error prevention software for the entry of physician medication orders. The CPOE standard has remained unchanged since our previous report. Also, there is little new evidence regarding the effectiveness of CPOE or the baseline incidence of serious medication errors. New data does suggest that hospital adoption of CPOE technology is increasing but remains low overall.

Based on a survey from 2001, 94% of US hospitals did not meet the CPOE standard, creating a population at-risk of 30 million patients. According to the best evidence, CPOE decreases serious medication errors by 55%. We estimate that universal implementation of CPOE would avert approximately 567,000 serious medication errors each year in the United States. Based on a more recent study by Bates et al. suggesting an 88% error reduction rate, a substantially greater number of

errors (907,677) could be potentially averted. Although a large proportion of serious medical errors are life threatening, the numbers that result in fatalities cannot be determined precisely from the medical literature. Accordingly, we did not calculate the number of deaths potentially avoided by CPOE. However, if only 0.1% of such errors were fatal, nearly 600 deaths would be avoided every year. If the fatality rate were 1%, nearly 6000 deaths would be avoided.

Evidence-based hospital referral: High-risk surgery

Evidence-based hospital referral (EHR) for high-risk surgery is based on the selective referral of patients to hospitals that meet certain quality standards for five operations. The quality measures previously focused only on minimum volume standards but have been expanded in 2003 to include processes of care and direct outcomes measurement. Also, because of new information on the strength of their volume-outcome relationships, Leapfrog has dropped carotid endarterectomy and added pancreatic resection to its list of operations. The 2003 standards for AAA repair, CABG and PCI now include documented adherence to certain clinical processes of care known to improve outcomes. For coronary artery bypass grafting (CABG) and percutaneous coronary interventions (PCI), risk-adjusted mortality rates have also been incorporated into the standards.

The proportion of the population at hospitals not meeting the EHR standards varied from 43% for PCI to 78% for CABG. The potential mortality reduction with EHR also differed across operations and was greatest for CABG (59%) and the smallest for AAA repair (37%). We estimate that implementation of EHR for these 5 surgical procedures would save approximately 7,602 lives each year in the US. The greatest number of deaths would be prevented with CABG (4,089 deaths annually), followed by PCI (2,800), and elective AAA repair (356). EHR would save 180 and 177 lives, respectively, with esophageal resection and pancreatic resection. The addition of process and outcomes measures to the previous volume standards has significantly increased the potential benefits of full implementation of EHR across the U.S. (2,581 in our previous analysis). The majority of the increase can be attributed to more precise classification of high quality centers using risk-adjusted mortality for CABG and PCI, by far the two most common procedures.

Evidence-based hospital referral: High-risk neonatal intensive care

The evidence-based hospital referral (EHR) standard for neonatal intensive care is based on selective referral of high-risk infants and deliveries to hospitals that meet minimum volume standards and demonstrate adherence to a new process of care measure. The EHR standard for neonatal care is directed to mothers of infants with very low birth weight (VLBW), very premature infants (<32 weeks gestational age), or those with a pre-natal diagnosis of major congenital anomaly. The newly incorporated process of care measure requires the documented use of antenatal steroids to the mothers of eligible infants.

Based on estimates from the state of California, 82% (45,954) of infants with congenital anomalies and 74% (57,737) of VLBW and/or very premature infants are born at hospitals that do not meet the standards. With EHR, there is an approximately 30% mortality reduction with referral to a higher volume NICU and a 40% mortality reduction with the use of antenatal steroids. We estimate that full implementation of EHR nationwide for high-risk neonatal intensive care would save approximately 3,606 lives each year in the U.S.. VLBW and/or very premature infants comprise the majority of lives saved (3,766 lives); infants with major congenital anomalies comprise the remainder (551 lives). Within the former group, the increased use of antenatal steroids, contributes significantly to the total number of lives saved (405 lives).

ICU physician staffing

The Leapfrog Group's ICU physician staffing (IPS) standard requires that physicians with specialized experience in critical care medicine manage or co-manage patients in the ICU. These physicians, called intensivists, must be present in the ICU during daytime hours and at other times should be able to return pages within 5 minutes or arrange for on-site physicians or physician extenders who can reach ICU patients within 5 minutes. The IPS standard has changed in 2003 to include the pediatric population.

Currently in the US, 79% (1,473,085) of admissions to adult ICUs and 51% (73,500) of admissions to pediatric ICUs occur in settings that do not satisfy the IPS standard. New evidence from a structured literature review shows that a 30% reduction in mortality could be achieved with increased ICU physician staffing. We estimate that full implementation of intensivist model staffing would save approximately 54,133 lives (1,102 children and 53,031 adults) each year in the US. As expected, for both the adult and pediatric population, the number of lives saved varies according to assumptions about the effectiveness of intensivist model staffing. For example, assuming a 10% relative mortality reduction, 18,000 adult lives would be saved. In contrast, assuming a 50% mortality reduction would save over 90,000 adult lives.

Computer physician order entry

Overview

The Leapfrog Group's standard for computer physician order entry (CPOE) requires hospitals to assure that at least 75% of hospital medication orders are entered through a computer system that includes prescribing-error prevention software and can alert physicians of at least 50% of common, serious prescribing errors. Hospitals must also require that physicians electronically document a reason for overriding an interception generated by the CPOE system.

There is relatively little new evidence since our last report regarding the efficacy of CPOE or the incidence of serious medical errors in hospitalized patients. However, new data does suggest that hospital adoption of CPOE technology is increasing but remains low overall: the proportion of patients at hospitals meeting the Leapfrog CPOE standard increased from 2% to 6% between 1997 and 2001.[2,3]

In the updated baseline analysis, universal implementation of CPOE would avert approximately 567,000 serious medication errors each year in the United States (Figure 1). The proportion of serious medical errors that result in fatality cannot be determined precisely from the medical literature. However, if only 0.1% of such errors were fatal, nearly 600 deaths would be avoided by CPOE every year. If the fatality rate were 1%, almost 6000 deaths would be avoided every year. In the following sections, we describe the methods and assumptions used in our analysis.

Methods and assumptions

The approach we used to estimate the number of serious medication errors potentially averted by full implementation of CPOE is illustrated in Figure 1. We first determined the population of inpatients who stand to benefit by the policy. We then calculated their baseline risk of serious medication errors and the reductions expected with CPOE.

Number of patients currently admitted at hospitals without CPOE. Based on data from the Nationwide Inpatient Sample (NIS),[1] 37,187,641 patients were admitted to non-federal, acute care hospitals in 2001. To avoid problems with health care access in rural areas, The Leapfrog Group is restricting CPOE, along with the other safety initiatives, to metropolitan areas. According to data from the NIS, hospitals in metropolitan areas accounted for 84% of all hospital admissions.[1]

We used new data to estimate the proportion of patients currently being treated at hospitals without CPOE. In our original report we estimated that only 2% of hospitalized patients were in hospitals with CPOE, based on a 1997 survey by Ash et al.[2] A more recent survey conducted in 2001 by the American Society of Health-System Pharmacists (ASHP) revealed that 4.3% of hospitals had computer physician order entry.[3] However, this proportion varied significantly according to hospital size. For instance, only 1.5% of hospitals with fewer than 50 beds had CPOE, compared to 20.4% at hospitals with more than 400 beds. Using data from NIS and appropriate weighting techniques, we estimate that 15% of hospitalized patients are treated in hospitals with CPOE systems on site (Table 2). Not all hospitals meet the Leapfrog Standard of having more than 75% of orders entered via CPOE. Among those hospitals with CPOE in the 2001 survey, only 35% met this requirement (Table 2). Thus, we estimate that only 6% of patients are currently treated in hospitals with CPOE systems meeting Leapfrog criteria.

Baseline rate of serious medication errors. A serious medication error is a non-intercepted error in the process of ordering, dispensing, or administering a medication that causes or has the potential to cause an adverse drug event.[4] In two studies by Bates et al at a single teaching hospital,[4,5] such errors occurred at a rate of 10.7 and 7.6 per 1,000 pt-days. Expressed in terms of incidence rates per admission, 5.1% and 3.4%, respectively, of hospitalized patients experienced at least one serious medication error. In our baseline analysis, the more conservative (lower) error rate of 7.6 per 1,000 pt-days was used. Thus, approximately 1,031,452 serious medication errors occur every year in US hospitals without CPOE.

Efficacy of CPOE. There is considerable literature describing the effectiveness of electronic clinical decision support systems in different contexts, as summarized recently by Kaushal et al.[6] A smaller number of studies have focused specifically on CPOE.[6-9] (Table 3) For this analysis, we relied exclusively on two studies conducted by Bates et al (Table 1), the only studies using serious medical errors as outcome measures. In the first study of over 2,000 admissions at a single academic medical center, serious medication errors fell from 10.7 to 4.9 per 1000 patient-days after implementation of CPOE (55% reduction).[4] In the second study (using later generation software with more advanced decision support), the proportion of patients experiencing serious medication errors fell from 7.6 to 1.1 per 1000 pt-days (88% reduction).[5] The more conservative estimate of CPOE efficacy (55%) was used in our baseline analysis.

Results

In our baseline analysis, we estimate that full implementation of CPOE would avert approximately 567,298 serious medication errors each year in the US. As expected, the number of errors avoided varied according to the efficacy of CPOE. (Figure 2) Although we were conservative in our baseline analysis (55% reduction in error rate with CPOE), assuming higher levels of effectiveness would have significantly increased the estimates of serious medication errors avoided. For instance, if the greater relative risk reduction (88%) seen in the more recent study by Bates et al is used for estimation, 907,677 medical errors are potentially averted (Figure 2).

Cautions and policy considerations

The number of serious medication errors that would be avoided if CPOE were implemented at all US hospitals depends on assumptions about the baseline error rate and the effectiveness of CPOE in avoiding errors. Our estimates of these parameters have several limitations. We estimated the baseline rate of serious medication errors from two studies at a single large teaching hospital (Brigham & Women's Hospital in Boston).[4,5] Whether errors rates from this large academic center can be safely generalized to other settings is uncertain. Because of the relatively complex case-mix at such centers, some would argue that the baseline medication error rate might be higher than the average rate at other hospitals. Alternatively, many teaching hospitals have a reputation for excellence in faculty and house staff and could have lower than expected medication error rates. To be conservative in our final estimates, we used the lower medication error rate from the two studies by Bates et al.[4,5]

There is also uncertainty about the effectiveness of CPOE in averting serious medication errors, which depends on both the characteristics of the software employed and each hospital's implementation skill. To be conservative in this analysis, we use the estimate that CPOE caused a 55% error reduction rate from the original report by Bates et al., which assessed a 1994-95 CPOE system. However, the quality of decision support in current CPOE systems has no doubt improved considerably, as evidenced by the follow-up study by the same group, which

demonstrated an 88% error reduction rate. For this reason, this analysis likely underestimates the number of serious medication errors that might be averted with full implementation of CPOE in US hospitals.

In focusing on its ability to reduce serious medication errors, this analysis does not provide a full accounting of the costs and benefits of CPOE. Costs are substantial and represent a significant barrier to CPOE implementation at many hospitals. As summarized previously, costs associated with implementing CPOE include system costs (establishing an appropriate information system platform and acquiring and integrating the necessary software and end-user hardware) and costs related to clinician time (content development, activation and training, and longitudinal oversight).[10] The total cost of implementing at an individual hospital depends on numerous variables and no doubt varies widely. Estimates of upfront costs vary from as low as $500,000 to almost $15 million per hospital. There is a similar spread between best- and worst-case scenarios for longitudinal costs, from $200,000 to $2 million per year.

Acting to offset these costs are the potential savings from fewer medication errors and adverse drug events, estimated to range between approximately $180,000 and $900,000 per year, depending on hospital size.[10] The potential of CPOE to reduce resource utilization in other ways is likely a more important source of savings. These sources of savings include medication substitution, reduced laboratory testing and imaging, increased use of clinical pathways, and gains in clinician efficiency. Although these savings are difficult to quantify and likely vary widely by hospital, some hospitals that have implemented CPOE report annual savings exceeding $5 million.[10]

A full accounting of the potential benefits of CPOE would optimally consider patient outcomes (such as mortality, injury and disability), not simply errors averted. Unfortunately, the likely effects of CPOE on patient mortality and disability rates cannot be determined directly from the literature. However, in the two studies by Bates et al,[4,5] more than half of all serious medication errors resulted in preventable adverse drug events. Approximately 20% of preventable adverse drug events were considered "life threatening" upon clinical review, but no patient in the two studies died as a direct result of a medication error. The two studies lacked sufficient sample size to detect a small but clinically meaningful reduction in mortality rates with CPOE. Ultimately, large, multi-center studies will be needed to better characterize relationships between medication errors and mortality. However, if only 1% of serious medication errors were fatal, we estimate that nearly 6,000 deaths would be avoided every year by full implementation of CPOE across all US hospitals.

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Figure 1: Calculating the number of serious medication errors avoided in the United States with universal implementation of Leapfrog's standard for computer physician order entry (CPOE).

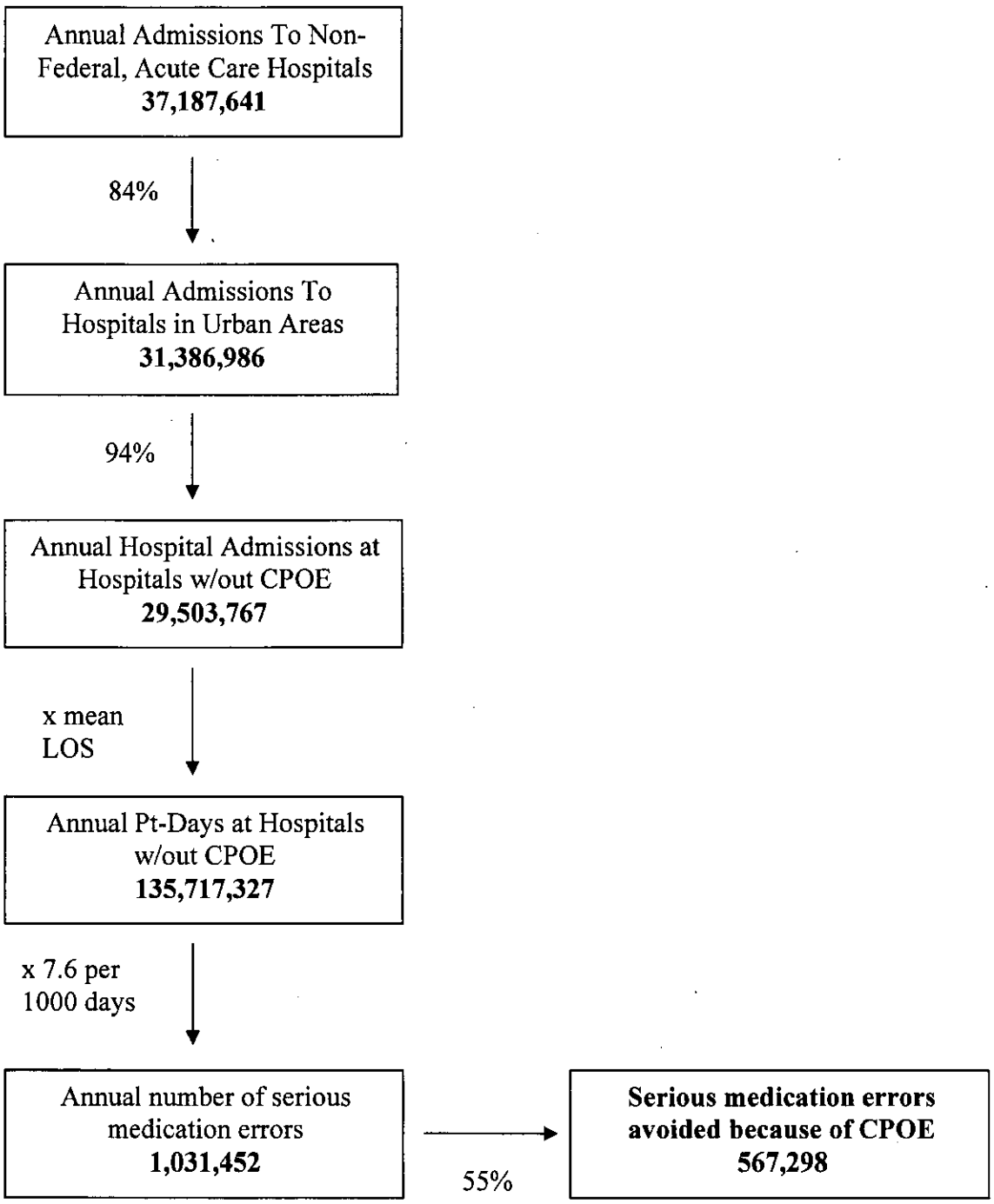


Table 1: Studies assessing the effectiveness of computer physician order entry (CPOE) in reducing serious medication errors. A serious medication error is an error in the process of ordering, dispensing, or administering a medication, that causes or has the potential to cause an adverse drug event; it does not include intercepted potential ADEs. Both studies were conducted at Brigham and Women's Hospital, Boston, MA.[3-4]

Study Participants		Rate of Serious Medication Error (per 1000 pt-days)		
Before CPOE	After CPOE	Before CPOE	After CPOE	Relative Risk Reduction
6 services chosen randomly from 23 available medical, surgical and intensive care units (2491 admissions)	Same 6 services plus 2 chosen randomly from same 23 available units (2047 admissions)	10.7	4.9	55%
3 general medical services (379 admissions)	Same 3 general medical services (475 admissions)	7.6	1.1	88%

Table 2: Relationship of hospital bed-size and the implementation of CPOE in a national sample of hospitals. Data are from the 2001 American Society of Health-System Pharmacists (ASHP) survey of prescribing and transcribing.

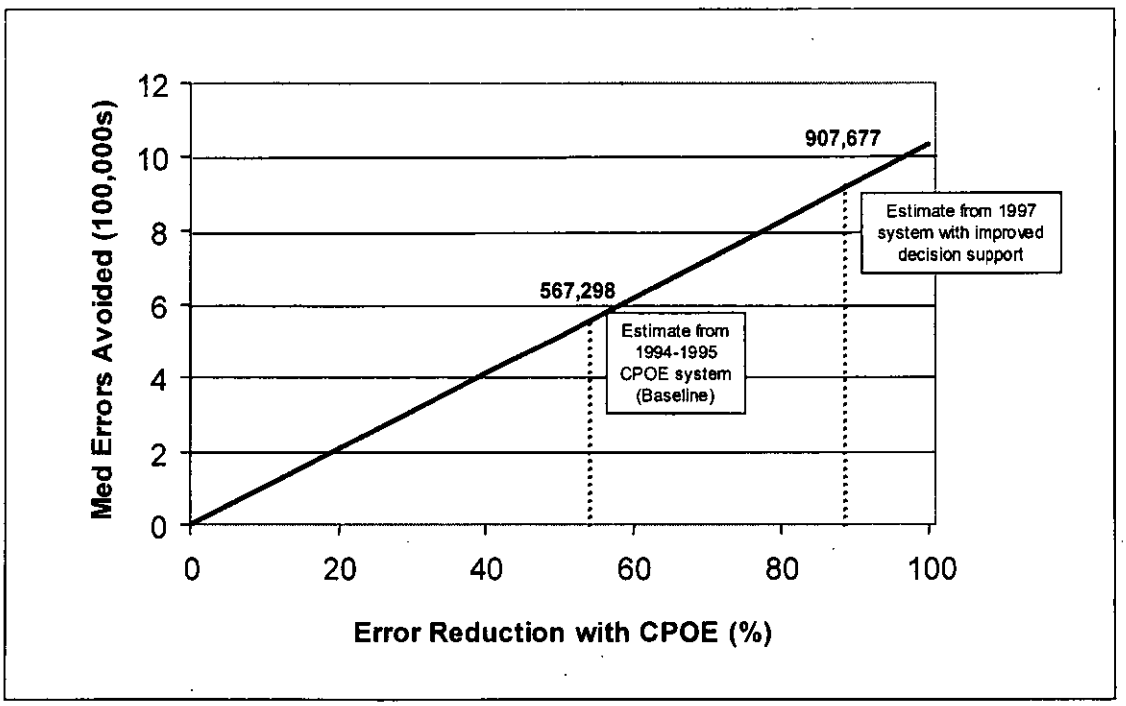
Hospital Bed-Size		Hospital Admissions According to Bed-Size Category*	Overall Percentage of Hospitals Without CPOE	Hospital Admissions without CPOE according to Leapfrog Standard**
Small	Up to 299	4,150,675 (11.2%)	98%	4,121,620
Medium	300 to 399	9,884,636 (26.6%)	90%	9,538,674
Large	≥400	23,152,330 (62.3%)	80%	21,531,667
		Total		35,122,504 (94%)

*Data taken from 2001 version of the Nationwide Sample and national estimates calculated using hospital sampling weights.
**Of hospitals that had CPOE, only 35% met the Leapfrog Standard of having more than 75% of orders entered via CPOE.

Table 3: Inclusive review of studies assessing the effectiveness of computer physician order entry on several different outcomes. The table was adapted from Kaushal et al.[6]

Study Authors	Description	Patients	Outcomes	Findings
Bates et al, 1998[4]	Observational study at tertiary care center comparing event rates between units and compared to historical controls	6,771 adult inpatients on medical, surgical, and intensive care wards	Serious medication errors and adverse drug events	55% decrease in serious medication errors
Bates et al, 1999[5]	Observational study at tertiary care center comparing event rates before and after implementation of CPOE	1,817 adult inpatients on 3 medical wards	Medication errors and adverse drug events	81% decrease in medication errors
Chertow et al, 2001[7]	Randomized trial at a tertiary care center of CPOE with decision support to adjust drug dose and frequency with renal insufficiency	7,490 adult inpatients with renal insufficiency	Inappropriate drug dose and frequency	13% decrease in inappropriate dose and 24% decrease in inappropriate frequency
Overhage et al, 1997[8]	Randomized trial at a teaching hospital assessing the impact of CPOE reminders for corollary orders	2,181 adult inpatients in a general medical ward	Omission of corollary orders (ie, drug levels when ordering gentamicin)	25% improvement in corollary orders
Teich et al, 2000[9]	Observational study at tertiary center comparing event rates before and after CPOE with decision support aimed at five prescribing practices	All adult inpatients	Changes in five prescribing practices (ie, heparin for patients with bed-rest orders)	Improvement in all five prescribing practices

Figure 2: Sensitivity analysis demonstrating the effect of different assumptions about the effectiveness of CPOE on the number of patients avoiding medication errors each year in the United States.



Evidence-Based Hospital Referral: High-Risk Surgery

Overview

The Leapfrog Group's evidence-based hospital referral (EHR) standard for high-risk surgical procedures has undergone significant change since our previous report (Table 1).

- Leapfrog updated the list of procedures. Leapfrog added pancreatic resection, for which hospital volume has a dramatic effect on mortality. Given new evidence showing little hospital volume effect for carotid endartectomy, Leapfrog removed it from the list. Coronary artery bypass grafting (CABG), percutaneous coronary interventions (PCI), elective abdominal aortic aneurysm (AAA) repair, and esophageal resection remain on the list.
- Incorporation of direct outcome measures. For CABG and PCI, hospitals must demonstrate acceptable risk-adjusted mortality rates, as judged by approved state- or national-level reporting systems, to satisfy the Leapfrog standards for EHR. Hospitals no longer receive full "credit" based on volume criteria alone.
- Incorporation of process of care measures. For CABG, PCI, and elective AAA repair, Leapfrog has incorporated process of care measures into its EHR standards. For these procedures, both minimum volumes and compliance with target process measures are included in the standard.

In our updated analysis, we estimate that implementation of EHR for these 5 surgical procedures would save approximately 7,602 lives each year in the United States. The greatest number of deaths would be prevented by appropriate referrals for coronary artery bypass grafting (4,089 deaths annually), followed by percutaneous coronary interventions (2,800) and elective AAA repair (356). The potential benefit of EHR for these procedures is substantially greater than estimated in our previous report, an increase largely attributable to augmenting the previous volume standards with outcome and process measures. EHR would save 180 and 177 lives, respectively, with esophageal resection and pancreatic resection.

Summary of Methods

We calculated the potential benefits of EHR assuming that all patients in the US underwent surgery at a hospital that was fully compliant with the new Leapfrog EHR standards. To avoid access issues and other unintended negative consequences in rural areas, The Leapfrog Group restricts EHR implementation to urban areas. Since the standards differ for each procedure, the methods for calculating potential lives saved vary by procedure and are described separately. However, our general approach involved two steps. First, we estimated the population at-risk, which includes all patients currently having surgery at hospitals not fully adherent to the Leapfrog standards. Second, we incorporated information about the mortality reduction associated with each volume, process, or outcome standard to estimate the potential lives saved.

For most of our analyses, we relied on primary data from the 2000 Nationwide Inpatient Sample (NIS). The NIS is a 20% stratified sample of hospital discharges in the US and is maintained by the Agency for Healthcare Research and Quality (AHRQ) as part of the Healthcare Cost and Utilization Project (HCUP).[1] To ensure the representative nature of the database, the NIS is stratified by geographical region, hospital bed size, teaching status, urban vs. rural location, and hospital ownership.

We obtained estimates pertaining to volume and mortality using NIS data. Because information on process variables is not available from the NIS, we obtained these parameters from the literature.

Results

Pancreatic Resection (Table 2). During the year 2000, there were 5,779 pancreatic resections performed in the US. Based on data from the NIS, 95% of pancreatic resections are performed in urban centers (Table 2).

The Leapfrog standard for pancreatic resection is based exclusively on minimum volume standards (11+/yr). According to 2000 NIS data, 62% of pancreatic resections were performed at hospitals not meeting this standard (Table 2).

In estimating mortality reductions likely to be achieved with EHR for pancreatic resection, we relied on risk-adjusted mortality rates derived directly from the NIS. Using the updated volume cut-offs, we calculated the adjusted rates of in-hospital death after adjusting for age, gender, race, coexisting diseases, and urgency of admission. Adjusted mortality rates were substantially lower at hospitals meeting the Leapfrog volume standard (5.0%) than at hospitals not meeting it (10.3%) (Figure 1).

We estimate that 344 deaths occur each year with this procedure at hospitals not meeting the EHR standard. Assuming the mortality rates observed at hospitals exceeding the standard, only 167 deaths would have occurred had these procedures been referred to higher volume hospitals. Thus, full implementation of EHR for pancreatic resection would save 177 lives each year in the US (Table 2).

Esophageal Resection (Table 3). As with pancreatic resection, the Leapfrog standard for esophagectomy is based exclusively on minimum volume standards. Based on 2000 NIS data, 4,350 patients undergo this procedure each year in the US with 95% in urban centers (Table 3).

Approximately 74% (3,058) of patients currently undergo esophagectomy at centers performing fewer than 13 per year. Adjusted mortality rates were markedly higher at such hospitals (11.1%) than hospitals exceeding Leapfrog volume criteria (5.2%) (Figure 1).

With these mortality rates, we would expect 339 deaths to occur without EHR and 159 deaths with EHR (Table 3). Thus, with full implementation of EHR for esophageal resection, 180 lives would be saved each year in the US (Table 3).

Abdominal Aortic Aneurysm Repair (Table 4). To comply fully with the Leapfrog standard for elective AAA repair, hospitals must perform more than 50 procedures per year and demonstrate at least 80% adherence to two process measures: beta-blockers in perioperative period and beta-blockers prescribed at discharge (Table 1). Based on 2000 NIS data, 41,667 patients underwent AAA repair in the US with 95% in urban centers (Table 4). Patients with ruptured AAAs are unstable and often need surgery at the hospital to which they first present. For this reason, the Leapfrog EHR standards do not pertain to patients with ruptured AAAs. To estimate the number of elective (non-ruptured) AAA repairs subject to EHR, we excluded patients that had a diagnosis of ruptured aneurysm or those that underwent emergent repair (22% of total AAA repairs).

As derived from the NIS, 48% of patients currently undergo AAA repair at hospitals performing fewer than 50 procedures per year. Adjusted mortality rates were significantly higher at such hospitals (5.1%) than at hospitals exceeding Leapfrog volume criteria (3.8%) (Figure 1). Thus, based on volume criteria alone, full implementation of EHR for AAA repair would potentially save 247 lives each year in the US (Table 4).

We then assessed the number of lives potentially saved by increasing the use of perioperative beta-blockers, a practice known to lower the risk of cardiac events and death after major vascular

surgery. The proportion of patients currently receiving beta-blockers with this procedure is unknown.[2] One large observational study found that only 30% of patients were receiving beta-blockers.[3] Since better processes of care likely underlie observed volume-outcome effects with AAA repair, we assumed that high volume hospitals would have a higher rate of beta-blocker use. Thus, for this analysis, we assumed a baseline adherence of 50%. The Leapfrog standard requires that at least 80% of patients receive the process of care in order for a hospital to be fully compliant. As a result, an additional 30% of patients would experience the benefit of mortality reductions associated with beta-blocker use.

How large is the benefit associated with beta-blocker use? Several randomized trials on the efficacy of beta-blockers in the perioperative period have demonstrated a 50% to 80% reduction in short-term and long-term mortality rates. However, these trials focused only on patients at high risk for cardiac events.[3] Thus, the benefit of perioperative beta-blockers for average-risk patients having AAA repair is not known. One large observational study demonstrated a 70% risk reduction in the combined endpoint of myocardial infarction and mortality, but did not provide risk reductions for mortality alone.[4] To be conservative, we assumed a relative risk reduction of 50% for our calculations. We then applied this risk reduction to an additional 30% of patients (50% baseline increased to 80%) undergoing surgery at high volume hospitals, yielding an additional 109 lives saved. Thus, a total of 356 lives would be saved each year with Leapfrog's EHR standard for AAA repair (Table 4).

Coronary Artery Bypass Grafting (Table 5). Leapfrog's updated EHR standards for coronary artery bypass grafting (CABG) are based primarily on referral to hospitals with lower risk-adjusted mortality rates. The process measures for CABG and PCI were not included in our estimates since they are not necessary for full compliance. At present, only four states (NY, NJ, PA, CA) have rigorous (e.g., audited) systems in place for assessing risk-adjusted mortality rates and reporting them publicly. In these states, hospitals must be in the best performing quartile (below the 25th percentile) of mortality rates to meet the Leapfrog EHR standard (Table 1). In other states, hospitals must meet a minimum volume standard (>450 cases per year) AND participate in the Society of Thoracic Surgeons (STS) database of risk-adjusted mortality AND have a risk-adjusted mortality rate lower than the national average to comply fully with the updated EHR standards (Table 1).

According to the 2000 NIS, 394,165 patients underwent CABG each year in the US with 97% in urban centers (Table 5). Given that the criteria for full adherence to the Leapfrog EHR standards differ according to the availability of public information on CABG outcomes, we present the results for each analysis separately.

NY, NJ, PA, CA. Given that 26% of the US population resides in these 4 states,[5] we estimate that 99,005 CABG operations are performed each year in these 4 states (Table 5). We determined mortality rates for each hospital in the NIS. We then divided hospitals into four equally sized groups (quartiles) based on their mortality rates. The average mortality rates within each quartile were 1.7% (1st quartile), 3.0% (2nd quartile), 4.0% (3rd quartile), and 6.1% (4th quartile). Collectively, hospitals in the last 3 quartiles (who cared for 78% of all patients) had an average adjusted mortality rate of 4.1%.

In the status quo, we would expect 3,166 deaths at hospitals in the 2nd through 4th quartiles. Assuming instead the mortality rate observed in 1st quartile hospitals, only 1,312 deaths would occur. Thus, Leapfrog's EHR standard for CABG would potentially avert 1,854 deaths in these four states alone.

Other States. Since 74% of the US population resides outside these states, we estimate that 281,785 CABG procedures occur in states without public reporting systems for cardiac

surgery (Table 5). Based on data from the 2000 NIS, approximately 39% of patients undergo CABG at hospitals that perform at least 450 cases per year AND have a mortality rate lower than the national average. The overall mortality rate for these hospitals was 2.7%. The remaining 61% of patients undergo CABG at hospitals not meeting the Leapfrog EHR standards, whose average mortality rate is 4.0%. In the status quo, 6,876 deaths occurred in this latter group. Assuming instead the 2.7% mortality observed in hospitals meeting the EHR standard, only 4,641 deaths would have occurred.

Thus, full implementation of the Leapfrog standards for CABG in these 46 states would save a total of 2,235 lives each year in the US. Including our estimates from the 4 states with public reporting systems, a total of 4,089 CABG deaths would be averted overall.

Percutaneous Coronary Intervention (Table 5). The updated EHR standards for percutaneous coronary intervention (PCI) are based on referral to hospitals that both meet minimum volume standards and also have low risk-adjusted mortality rates. However, unlike CABG, no statewide systems are currently in place for assessing risk-adjusted mortality rates for PCI. Thus, to comply fully with the EHR standard for PCI, hospitals must meet a minimum volume standard (>400 cases per year) AND participate in the American College of Cardiology (ACC) database of risk-adjusted mortality AND have a risk-adjusted mortality rate lower than the national average (Table 1). According to the 2000 NIS, 678,296 patients undergo PCI each year in the US, with 96% in urban centers (Table 5).

Based on data from the 2000 NIS, approximately 57% of patients undergo PCI at hospitals that perform at least 400 cases per year AND have a mortality rate lower than the national average. The overall mortality rate for these hospitals was 1.0%. The remaining 43% of patients undergo PCI at hospitals not meeting the Leapfrog EHR standards, whose average mortality rate is 2.0%. In the status quo, 5,600 deaths occurred in this latter group. Assuming instead the 1.0% mortality observed in hospitals meeting the EHR standard, only 2,800 deaths would have occurred. Thus, full implementation of the Leapfrog standards for PCI would save a total of 2,800 lives each year in the US.

Summary of Results. Overall, we estimate that implementation of the new EHR standards for these 5 surgical procedures would save approximately 7,602 lives each year in the United States. The greatest number of deaths would be prevented with coronary artery bypass grafting (4,089 deaths annually), followed by percutaneous coronary interventions (2,800) and elective AAA repair (356). Estimates of potential lives saved were smaller after surgery for esophageal resection (180) and pancreatic resection (177) in part because these high-risk procedures occur less frequently.

Cautions and policy considerations

The addition of process and outcomes measures to the previous volume standards has significantly increased the potential benefits of full implementation of EHR across the US. In this analysis, we estimate that 7,602 lives could be saved with EHR, compared to 2,581 in our previous analysis of the volume-only standards. The majority of the increase can be attributed to more precise classification of high quality centers using risk-adjusted mortality for CABG and PCI, by far the two most common procedures. The use of one process measure—perioperative beta-blockers—also substantially increased the benefits of EHR for elective AAA repair.

Our estimates depend on several estimated parameters and significant assumptions. In assessing procedure-specific volume-outcome relationships, we used point estimates derived directly from a recent version of the NIS, a nationally representative sample of hospitals in the United States. The magnitude of volume-outcome effects used in this analysis were generally consistent with

those used in our previous report, which were derived from the "single best" study in the literature for each procedure, as defined by Dudley et al.[7] Further, estimates herein of volume-related mortality reductions are similar in magnitude to those in our more comprehensive analysis based on the national Medicare population.[8]

When considering the effect of selective referral to hospitals based on volume standards it is also important to consider the distinction between hospital and surgeon volume. Recent evidence has emerged exploring the contribution of individual surgeon experience to the relationship of hospital volume and mortality.[9] For some operations, such as carotid endarterectomy, surgeon volume accounted for a large proportion of the apparent hospital volume effect. However, the importance of surgeon volume varied according to the procedure. The Leapfrog EHR standard currently does not address the importance of surgeon volume. Future updates will likely incorporate individual surgeon volume standards into the criteria.

For elective AAA repair, our estimates of the potential benefits of EHR depend on assumptions about the effectiveness of perioperative beta-blockers. As described in one recent literature synthesis, there is little doubt that this practice is associated with reduced perioperative mortality, which may persist to at least one year postoperatively.[2-4] However, the magnitude of the effect is somewhat uncertain. The clinical trials focus on different populations with varying baseline risk. Our estimates of lives saved by this EHR standard also require assumptions about the current prevalence of this practice and to what extent it could be increased, both of which are uncertain.

For CABG and PCI, the potential benefits of EHR depend on the reliability of risk-adjusted mortality rates. No matter how rigorously they are assessed and risk-adjusted, estimates of a hospital's mortality rate will always be somewhat imprecise, particularly when baseline event rates are low. The net effect is that a high proportion of hospitals just above or below a given mortality standard will have confidence intervals that overlap the standard. Stated a different way, chance dictates that some hospitals with mortality rates below the standard will actually have a worse true mortality rate than some hospitals above it. Our analysis does not adequately deal with this issue—it assumes that measured mortality rates perfectly reflect performance. Thus, we have to some degree overestimated the lives likely to be saved by EHR for CABG and PCI.

Our estimates also raise a basic practical consideration: Is full implementation of EHR realistically feasible? For some procedures, the answer is yes. When hospitals in rural areas are excluded, all or most patients undergoing pancreatic resection or esophagectomy could be referred to hospitals meeting Leapfrog volume standards without imposing unreasonable travel burdens on patients.[10] These operations are also uncommon enough that EHR would not imply redistribution of large numbers of patients creating capacity problems at high volume hospitals. For elective AAA repair, there is little doubt that hospitals sufficiently motivated could increase the proportion of patients receiving perioperative beta-blockers. In contrast, the feasibility of full implementation of CABG and PCI is doubtful. Even if rigorous information about risk adjusted mortality rates were available for all hospitals, it would not be practical to move all patients to the 25% of hospitals with the best results. This would involve referral of hundreds of thousands of patients and present obvious capacity issues at receiving centers.

For this reason, incentives created by The Leapfrog Group for hospitals to measure and report their outcomes should be viewed in an additional context: quality improvement. Previous efforts in cardiac surgery and in the Department of Veterans Affairs suggest that the basic act of outcomes measurement and feedback of performance data to providers can result in dramatic reductions in surgical morbidity and mortality rates.[11-12] For some procedures, outcomes may be best improved by efforts aimed simply at getting patients to the best hospitals. For other procedures, however, it is important not to overlook the value of incentives that will stimulate improvement of quality at all hospitals.

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Table 1: Criteria for Full Adherence to the 2003 Leapfrog EHR Safety Standards.

Procedure	Volume Standard	Process Measures	Outcomes Measures
Pancreatic Resection	11/yr	None	None
Esophageal Resection	13/yr	None	None
AAA Repair	50/yr	Perioperative beta-blockers Beta-blockers prescribed at discharge	None
Coronary Artery Bypass Grafting			
NY, NJ, PA, CA*	None	(beta-blockers, use of IMA, aspirin, lipid lowering therapy and early extubation when appropriate)**	Must be in the lowest quartile of mortality rates in the state
Other States	450/yr	(beta-blockers, use of IMA, aspirin, lipid lowering therapy and early extubation when appropriate)**	Must participate in STS database AND have mortality rate below the national average
Percutaneous Coronary Intervention	400/yr	(Aspirin on discharge, intervention within 90 minutes for AMI)**	Must participate in ACC database AND have mortality rate below the national average

*NY, NJ, PA, CA have prospective outcomes registries for coronary artery bypass grafting and percutaneous coronary interventions.
**Used in partial credit algorithms for hospitals not meeting the criteria for full adherence to the Leapfrog EHR standards.

Figure 1: Adjusted mortality rates at hospitals above and below Leapfrog volume criteria. Analysis based on data from the Nationwide Inpatient Sample (2000). Mortality rates are adjusted for age, gender, race, admission acuity, and coexisting diseases. The differences between high and low volume hospitals are statistically significant (P<.05) for all five procedures.

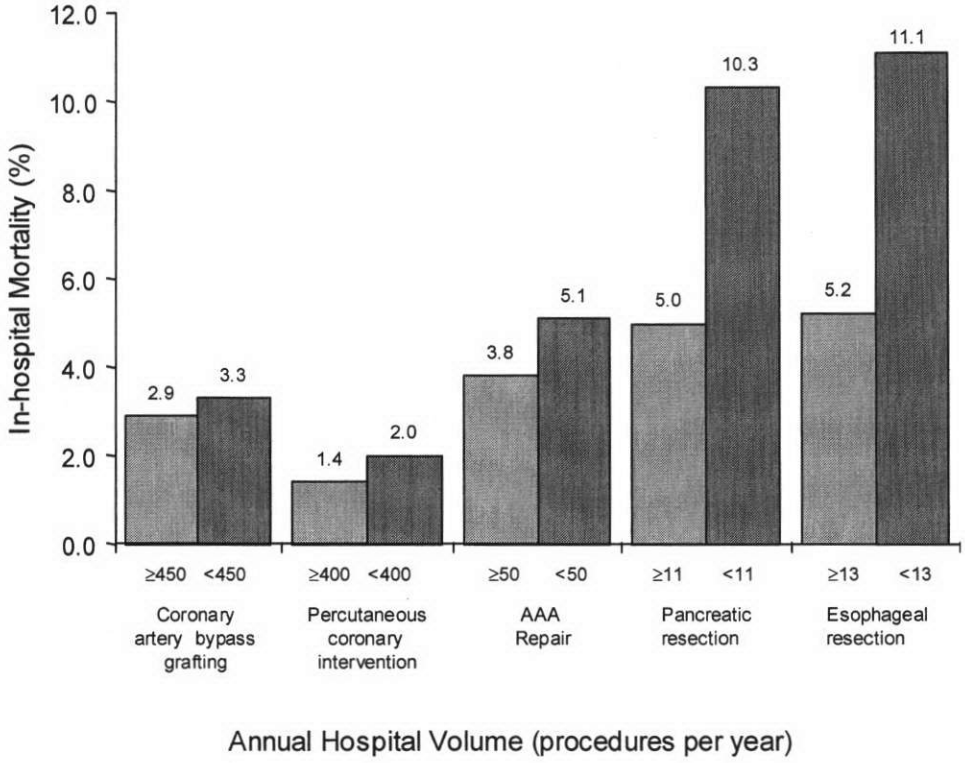

Table 2: Number of lives potentially saved by implementation of EHR for pancreatic resection.

Pancreatic Resection

	Inputs and Assumptions	Annual Number
Number of annual cases in US hospitals	2000 NIS	5,779
Number in urban hospitals	96% in urban setting (2000 NIS)	5,548
Patients at low volume hospitals (LVHs) (population at-risk)	62% of patients (2000 NIS)	3,340
Expected deaths without EHR	10.3% (mortality rate at LVHs) of 3,340	344
Expected deaths with EHR	5.0% (mortality rate at HVHs) of 3,340	167
Lives saved by EHR		177

Table 3: Number of lives potentially saved by implementation of EHR for esophageal resection.

Esophageal Resection

	Inputs and Assumptions	Annual Number
Number of annual cases in US hospitals	2000 NIS	4,350
Number in urban hospitals	95% in urban setting (2000 NIS)	4,132
Patients at low volume hospitals (LVHs) (population at-risk)	74% of patients (2000 NIS)	3,058
Expected deaths without EHR	11.1% (mortality rate at LVHs) of 3,058	339
Expected deaths with EHR	5.2% (mortality rate at HVHs) of 3,058	159
Lives saved by EHR		180

Table 4: Number of lives potentially saved by implementation of EHR for abdominal aortic aneurysm repair.

Abdominal Aortic Aneurysm Repair

	Inputs and Assumptions	Annual Number
Number of annual cases in US hospitals	2000 NIS	41,667
Number in urban hospitals	95% in urban setting (2000 NIS)	39,586
Patients at low volume hospitals (LVH) (population at-risk)	48% in LVHs (2000 NIS)	19,001
Expected deaths without EHR	5.1% (mortality at LVHs) of 19,001	969
Expected deaths with implementation of volume standard	3.8% (mortality at HVHs) of 19,001	722
Expected deaths after implementation of beta-blocker standard	30% of patients experience additional 50% relative mortality reduction	613
Lives saved by volume standards		247
Lives saved from beta-blockers		109
Total lives saved with EHR		356

Table 5: Number of lives potentially saved by implementation of EHR for coronary artery bypass grafting surgery.

Coronary Artery Bypass Surgery

	Inputs and Assumptions	Annual Number
Number of cases in US hospitals	2000 NIS	394,165
Number in urban hospitals	97% in urban setting (2000 NIS)	380,790
NJ, NY, PA, CA		
Number of cases in these states	26% of US population (US census data)	99,005
Number of cases at hospitals with mortality > 25th percentile	78% of patients (2000 NIS)	77,224
Expected deaths without EHR	4.1% (mortality rate at all hospitals above 25th percentile) of 77,224	3,166
Expected deaths with EHR	1.7% (mortality rate at hospitals below 25th percentile) of 77,224	1,312
Lives saved by EHR		1,854
Other States		
Number of cases in other states	74% of US population (US census data)	281,785
Number of cases at hospitals not meeting EHR standards*	61% of patients (2000 NIS)	171, 889
Expected deaths without EHR	4.0% (mortality rate at hospitals not meeting EHR standard) of 171, 889	6,876
Expected deaths with EHR	2.7% (mortality rate at hospitals meeting EHR standard) of 171, 889	4,641
Lives saved by EHR	6,876 (deaths without EHR) x 0.33 (RRR) =	2,235
Total lives saved with EHR		4,089

*Hospitals must meet the volume threshold (>450 cases/year) and have mortality rates lower than the national average.

Table 6: Number of lives potentially saved by implementation of EHR for percutaneous coronary interventions.

Percutaneous Coronary Interventions

	Inputs and Assumptions	Annual Number
Number of cases in US hospitals	2000 NIS	678,296
Number in urban hospitals	96% in urban setting (2000 NIS)	651,164
Number of cases at hospitals that don't meet EHR standards*	43% of patients (2000 NIS)	280,000
Expected deaths without EHR	2.0% (mortality rate at hospitals not meeting EHR standard) of 207,201	5,600
Expected deaths with EHR	1.0% (mortality rate at hospitals meeting EHR standard) of 207,201	2,800
Lives saved by EHR		2,800

*Hospitals must meet the volume threshold (>400 cases/year) and have mortality rates lower than the national average.

Evidence-Based Hospital Referral: High-Risk Neonatal Intensive Care

Overview

The Leapfrog evidence-based hospital referral (EHR) standard for neonatal intensive care requires that high-risk deliveries be managed in neonatal ICUs (NICUs) with average daily census levels of 15 or more. Neonatal EHR applies to infants with very low birth weights (less than 1500g), infants delivered at gestational age less than 32 weeks and those with a pre-natal diagnosis of major congenital anomalies. Leapfrog's standards now requires adherence to a process of care measure for full compliance: the administration of antenatal steroids to mothers of eligible infants (Table 1).

We estimate that full implementation of EHR nationwide for high-risk neonatal intensive care would save approximately 3,606 lives each year in the US. Very low birth weight and/or very premature infants comprise the majority of lives saved (3,055 lives). Infants with major congenital anomalies comprise the remainder (551 lives) of lives saved. Within the former group, the increased use of antenatal steroids (405 lives) contributes significantly to the total number of lives saved.

Methods and Results

The number of lives potentially saved by full implementation of EHR for high-risk deliveries was calculated by first determining the number of deliveries (population at-risk) potentially affected by the policy. We then estimated baseline mortality risks for the high-risk groups and the potential mortality reductions associated with selective referral and use of antenatal steroids. According to the national birth report for 2001, there were 4,025,933 live births in the US. The high-risk infants included in the Leapfrog EHR standard are considered as two separate groups: 1) infants with major congenital anomalies and 2) very low birth weight (VLBW) and/or very premature infants. The number of lives saved with EHR for high-risk neonatal care was estimated for each group separately.

Infants with Congenital Anomalies (Table 2). The combined incidence of the congenital anomalies targeted by The Leapfrog Group is 1.6% (64,415 births) of live births each year in the US.[2] According to the Nationwide Inpatient Sample (NIS) for 2000, 87% of all births occur in urban hospitals. Based on data from the state of California, 82 percent of births involving major congenital anomalies occurred in non-regional (level 1, II, or II+) NICUs or in regional NICUs with average daily census rates below 15.[2]

Since 60% of deliveries involving major congenital anomalies are not detected by prenatal ultrasound[3-4], all of the births currently occurring in other settings would not be eligible for transfer to large regional NICUs prior to delivery. Thus, we assumed that only 40% of such deliveries could be moved to large regional NICUs (Table 2).

Our estimates of the efficacy of evidence-based hospital referral rely on one study examining mortality rates for high-risk deliveries in high volume and low volume NICUs.[5] The adjusted odds ratio of death at regional NICUs with an average daily census of 15 or more compared to all other facilities was approximately 0.67. Because the study did not present stratified results, we assumed the same relative benefit for the two high-risk subgroups.[2]

The mortality rate (within the first 28 days of life or first year of life if continuously hospitalized) for infants with congenital anomalies was 9.25%.[2] We determined mortality rates at non-regional NICUs (9.8%) and regional NICUs with average daily census of 15 or more (6.8%) based on the overall mortality rates and the mortality reduction associated with EHR as previously described.[2] Full implementation of EHR for infants with prenatal diagnosis of a major congenital anomaly would result in 551 lives saved each year in the US (Table 2).

Very Low Birth Weight and/or Very Premature Infants (Table 3). There is considerable overlap in the occurrence of VLBW and very preterm births. The incidence of very low birth weight (<1500g) and very premature infants (<32 weeks gestation) as determined from the 2001 National Birth Report were 1.44% (57,973 births) and 1.95% (78,506 births), respectively.[1] There is, of course, substantial overlap between these two groups. Based on stratified data from the National Birth Report[1], we estimated that 2.23% of live births have at least one of the two conditions.

Approximately 74 percent of births of VLBW and/or very premature infants occurred in NICUs with an average daily census rates below 15.[2] Most mothers experiencing premature labor will present to the nearest hospital or facility at which they have received prenatal care. Some with particularly advanced or precipitous labor will not be appropriate candidates for transfer for safety reasons. As in our previous report[2], we assumed that 10% of such women would not be appropriate for transfer (Table 1).

The mortality rate for VLBW and/or very premature infants, based on data from the state of California, was 16.8%.[2] We estimated mortality rates at non-regional NICUs (18.1%) and regional NICUs with average daily census of 15 or more (13.0%) based on the overall mortality rates and the mortality reduction associated with this volume-based EHR standard, as previously described (Table 2).[2] Full implementation of the standard for VLBW and/or very premature infants would result in 2,650 lives saved each year in the US (Table 2).

Adherence to antenatal steroids (Table 3). The Leapfrog EHR standard includes adherence to a new process measure for appropriate infants (Table 1). All mothers delivering between 24 and 33 6/7 weeks of gestational age should receive at least one dose of antenatal steroids.

Several randomized clinical trials have shown significant reductions in mortality among premature infants receiving antenatal steroids. A meta-analysis of 15 trials demonstrated an average mortality reduction of 40% when combined across trials.[7] For our calculations, the population at-risk is VLBW infants not currently receiving antenatal steroids. Recent data from the Vermont Oxford Network of NICUs demonstrated that 75% of VLBW infants received antenatal steroids.[8] Since predominantly large NICUs participate in this network, we applied this baseline rate of steroid use to NICUs meeting the volume-based EHR standard.

For our calculations, we assumed that the rate of adherence could be increased from 75% to 90% (not 100%). We made this conservative assumption for the following two reasons: 1) eligibility criteria for the volume-based standards and process measures are similar but not identical and 2) some infants may not be eligible for the process measures for other reasons. Thus, we assumed that an additional 15% of infants would be receiving antenatal steroids. Given a further mortality reduction of 40% among the 15% of infants, we estimate an additional 405 lives saved each year (Table 3).

Cautions and policy considerations

Estimates of the potential benefits of EHR for high-risk deliveries should be viewed cautiously. Compared to the evidence underlying other Leapfrog safety standards, research examining the variation in mortality rates across NICUs is relatively scant. By necessity, our analysis relied primarily on a single study based on California hospital discharge data.[5] Thus, it is important to consider the external validity of this study with regards to both the distribution of high-risk deliveries and the potential efficacy of volume-based hospital referral.

The calculation of lives saved due to use of antenatal steroids required several assumptions. Eligibility criteria for volume-based referral and antenatal steroids are similar but not identical. Because we could not determine the size of eligible population more precisely, we made conservative assumptions about the proportion of infants eligible. Despite the uncertainty in these assumptions,

however, our results suggest that a modest increase in the use of antenatal steroids will substantially increase the potential benefits of EHR.

Mechanisms underlying relationships between volume and outcome with neonatal intensive care are largely unknown. Mechanisms no doubt include greater utilization of specific processes of care (such as use of antenatal steroids) at higher volume centers. In our analysis, however, we assumed independent effects of volume-based referral and the greater adherence to the process measure. To the extent that the two may be related, however, our estimates may reflect some degree of "double-counting" in determining lives saved.

Although current evidence suggests that the Leapfrog EHR standards for NICU care could save many lives, further research on the epidemiology of high-risk deliveries and the efficacy of referral to higher volume NICUs is warranted. Studies should also strive to understand how differences in processes of care contribute to observed variation in mortality rates across neonatal ICUs.

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Table 1: Criteria for full adherence to the 2003 Leapfrog EHR Safety Standards for high-risk neonatal intensive care.

Condition	Volume Standard	Process Measures
Major congenital anomalies	Neonatal ICU with average daily census >15	None
Very low birth weight (<1500g) and/or very premature (<32 weeks)	Neonatal ICU with average daily census >15	Antenatal steroids*

*Infants born between 24 and 33 6/7 weeks are eligible.

Table 2: Number of lives potentially saved by implementation of EHR for infants with congenital anomalies.

Infants with Congenital Anomalies

	Inputs and Assumptions	Annual Number
Deliveries in US hospitals with congenital anomalies	1.6% of live births (CA state data)	64,415
Number in urban hospitals	87% in urban setting (2000 NIS)	56,041
Deliveries in urban hospitals that don't meet Leapfrog Standards	82% (CA state data)	45,954
Deliveries eligible for referral to NICU with average daily census of 15 or more	40% (detected on prenatal ultrasound)	18,382
Expected deaths without referral	9.8% (mortality rate before EHR)	1,801
Expected deaths with referral	6.8% (mortality rate after EHR)	1,250
Lives saved by EHR		551

Table 3: Number of lives potentially saved by implementation of EHR for very low birth weight and/or very premature infants.

Very Low Birth Weight and/or Very Premature Infants

	Inputs and Assumptions	Annual Number
Deliveries in US hospitals	2.23% (National birth report)	89,681
Number in urban hospitals	87% in urban setting (2000 NIS)	78,022
Deliveries in urban hospitals that don't meet Leapfrog Standards	74% (CA state data)	57,737
Deliveries eligible for referral to NICU with average daily census of 15 or more	90% (based on "clinical grounds")	51,963
Expected deaths without volume-based referral	18.1% (mortality rate before EHR)	9,405
Expected deaths with volume-based referral	13.0% (mortality rate after EHR)	6,755
Expected deaths after implementation of antenatal steroids standard	15% of patients experience additional 40% relative mortality reduction	6,350
Lives saved by volume standards		2,650
Lives saved from antenatal steroids		405
Total lives saved		3,055

ICU Physician Staffing

Overview

The Leapfrog Group's IPS safety standard requires that physicians with specialized experience in critical care medicine manage or co-manage patients in the ICU. These physicians, called intensivists, must be present in the ICU during daytime hours and provide clinical care exclusively in the ICU. At other times (at least 95% of the time), they should be able to return pages within 5 minutes or arrange for on-site physicians or physician extenders who can reach ICU patients within 5 minutes.

Updates since the publication of our previous report account for changes in the IPS Standard itself and publication of data on the efficacy of IPS from a structured literature review. A national advisory panel recently met to update the IPS Standard resulting in an expansion of the initiative to include pediatric ICUs. Thus, the current report includes estimates of potential lives saved for both adult and pediatric ICUs.

In our updated baseline analysis, we estimate that full implementation of IPS would save approximately 54,134 lives each year in the US. The effectiveness of IPS is due to the large number of deaths that occur in the ICU each year (over 200,000). Given the magnitude of the population at risk, even small improvements in ICU mortality rates save many lives. Although our analysis is based on the best data currently available, many of the variables used in our calculations cannot be estimated precisely. In instances of uncertainty, we selected values that biased our calculations downward. Thus, we believe our estimate of the number of lives likely to be saved by IPS is conservative. In following sections, we describe the methods and assumptions we used in our analysis.

Methods and Assumptions

The general strategy used to calculate the number of lives saved by full implementation of intensivist model ICUs is shown in Figure 1. The first step was determining the adult and pediatric populations at risk. Next, the baseline in-hospital mortality risks for each population and the potential mortality reductions associated with implementing intensivist model ICUs were estimated.

Current number of ICU admissions. To estimate the number of patients that could potentially benefit from the policy initiative we determined the number of patients admitted each year to non-intensivist ICUs (Figure 1). We could not directly determine the overall number of patients admitted to ICUs in the United States. Therefore, we determined ICU utilization rates for one state (Maryland) and extrapolated to the entire US. This method is different from that used in our previous report, which was based on the Medicare population and may have been an overestimate since the data include admissions to the postoperative recovery unit.

The total number of adult hospitalizations (18 or more years old) and children (<18 years) in the US were determined using weighted estimates from the Nationwide Inpatient Sample.[2] To avoid problems with health care access in rural areas, the Leapfrog Group is restricting the IPS Standard, along with the other safety initiatives, to metropolitan areas. In the Nationwide Inpatient Sample in 2001, 84% of patients were admitted to hospitals in urban areas.[2] The Maryland state data from 2002 revealed that 2.7% of children and 7.2% of adults were admitted to the ICU. Based on these calculations, we assumed in our analysis that 1,864,664 adults and 144,118 children are admitted to urban ICUs each year in the US.

The current proportion of ICUs in the US with intensivist models is unknown, but is thought to be low. In a 1991 national survey, only 22% of hospitals indicated that ICU order writing was restricted to unit staff (i.e., a "closed unit").[3] In a follow-up survey, the same group reported that 17% of ICUs had closed units with respect to order writing.[4] Neither study described the proportion of closed units in which all ICU staff were board-certified (or -eligible) in critical care medicine, or met other Leapfrog criteria. In the hospital survey (~60% response rate) conducted by the Leapfrog group, 21.4% (110 of 515) of hospitals in rollout areas responded that they fully meet the IPS standard.[5] In our baseline analysis, we assumed that 21% of all adult ICU patients are currently treated in ICUs meeting the Leapfrog standard. This assumption is likely an overestimate given that hospitals with IPS already in place are more likely to respond to the Leapfrog's survey.

In contrast to adults in ICUs, the pediatric population is more likely to be covered by a critical care specialist. In a national survey conducted in 1993 by Pollack et al, 201 of 301 hospitals with pediatrics ICUs responded and 48.5% of hospitals stated that they had a dedicated ICU physician available 24 hours per day.[6]

Current ICU Mortality. We estimated average in-hospital mortality rates for both adult and pediatric ICU patients from large cohort studies specific to each population. For adults, Zimmerman et al.[7] noted an overall 12.4% in-hospital mortality rate in 38,000 patients admitted to 161 hospitals between 1993 and 1996. In another study of adults by Shortell et al., in-hospital mortality for 17,000 patients at 42 randomly selected ICUs was 16.6% between 1988 and 1990.[8] In our baseline analysis, we selected 12% since it is the lower, more conservative of these two estimates. For pediatric ICUs the overall mortality is lower on average and was approximately 5% in two large cohort studies.[9,10]

Mortality reductions with implementing the intensivist model. Several previous studies have evaluated the effectiveness of higher intensity staffing models in reducing ICU mortality. In our previous report, we used the estimate from the single study showing the lowest efficacy, which showed a 15% relative mortality reduction. Using this low-end assumption regarding effectiveness provided a conservative estimate of the number of potentially averted deaths.

Since our last report on the benefits of universal adoption, high quality information synthesizing the previous evidence has become available. In a recent systematic review by Pronovost and colleagues, the mortality reduction for all studies combined was estimated and was found to be higher than the conservative estimate we used for the previous analysis.[1]

Pronovost's structured review found that 16 of 17 (94%) studies demonstrated a reduction in hospital mortality (Figure 2).[1,11-23] The weighted relative risk for in-hospital mortality with high intensity vs. low intensity IPS was 0.71 (95% CI, 0.62 to 0.82) (Figure 2). This combined estimate of a 30% risk reduction was used in our baseline analysis. The systematic review also estimated a 40% reduction in ICU mortality for studies that included this endpoint. In our analysis, we used the lower (more conservative) estimate of efficacy based on the overall hospital mortality analysis.

Two studies in the systematic review included pediatric patients and these both demonstrated larger mortality reductions than the combined estimate. Only one of these used in-hospital mortality as an endpoint yielding a relative risk reduction of 47%. To avoid an unstable estimate, the more conservative overall estimate of a 30% reduction was applied to the pediatric population as well (Figure 1).

Results

In our baseline analysis, we estimate that full implementation of intensivist model staffing would save approximately 54,134 lives (1,102 children and 53,031 adults) each year in the US (Figure 1). As expected, for both the adult and pediatric population, the number of lives saved varies according to assumptions about the effectiveness of intensivist model staffing (Figure 3 and Figure 4). For example, assuming a 10% relative mortality reduction, 18,000 adult lives would be saved with universal adoption of the IPS standard. In contrast, assuming a 50% mortality reduction would estimate over 90,000 adult lives saved.

Cautions and policy considerations

Given the large number of deaths that occur in ICUs each year in the United States (more than 200,000), even small reductions in ICU mortality rates would save many lives. Based on our updated analysis, if the Leapfrog initiative is successful in effecting full implementation of intensivist model ICU staffing in metropolitan areas nationwide, we estimate that approximately 53,031 adult's lives and 1,102 children's lives could be saved each year in the US. Despite changes in our assumptions regarding the effectiveness of IPS, the number of potential lives saved is similar to the estimate from our previous report. The smaller population at-risk in the current report offset the larger mortality reduction associated with IPS used in the baseline analysis.

The estimate of the effectiveness of IPS from the structured literature review is only as accurate as the original studies, which have several shortcomings in methodology that should be considered. First, many of them use historical controls and are limited by secular trend bias, with the mortality falling at those hospitals for reasons other than implementation of intensivist model staffing. The hospitals in these studies may have changed other aspects of care not directly related to physician staffing changes. Although there is no evidence that ICU mortality rates are declining, mortality rates with many clinical conditions are improving over time with advances in science and technology. However, given the magnitude of decline in mortality seen in many of these studies, it is very unlikely that improvements can be attributed to secular trend bias alone.

Second, estimates from studies with cross-sectional designs may suffer from imperfect risk-adjustment. Thus, their results may be partially confounded by unmeasured differences in characteristics of both patients and providers between control and intensivist model groups. For instance, few studies used physiologic data for risk adjustment, which is important given the severity of illness in the critically ill population. Also, hospitals with and without IPS may differ in other important areas such as availability of technology, nurse staffing, and hospital caseload. Third, most of these studies are from single hospitals or, at the most, limited geographic areas, and caution is required in generalizing these results to the entire US. Finally, there was substantial heterogeneity in the amount of intensivist involvement across the original studies. Some studies involved simply adding co-management by a single intensivist to a system primarily run by non-ICU based physicians; others described extensive changes in staff organization, including complete replacement of ward-based teams by intensivists and ICU-based house staff. It is important to note, however, that the Leapfrog IPS standard falls on the latter, "stricter" side of the spectrum, and thus is likely to be more efficacious.

Although the potential benefits are large, several barriers must be overcome to realize full implementation of intensivist model ICU staffing. Although workforce issues have not been studied carefully, it is unlikely that there are currently enough board-certified intensivists to staff ICUs fully at all hospitals.[24] In hospitals with small units, meeting the Leapfrog standard may increase net cost per stay. For these reasons, broad implementation of intensivist model ICU

staffing may require a blend of increased fellowship training slots in critical care, consolidation of small ICUs, and advances in telemedicine.

Many would argue that lives saved by intensivist model ICU staffing are not equivalent to lives saved by other public health interventions (e.g. seat belt laws). ICU patients often have substantial limitations in functional status and shortened life expectancies compared to the general population. For this reason, further research should consider how improvements in ICU care affect quality of life after hospital discharge and long-term survival.

Another significant barrier to full implementation of IPS is the expense of hiring additional staffing at each hospital. Salaries for intensivists, nurse practitioners, and physician assistants will result in large expenditures for hospitals. These costs, however, will be offset by savings from reductions in inappropriate ICU admissions, shortened ICU and hospital length of stay, and lower complication rates. Further, given the more than 50,000 lives saved from IPS, conservative estimates of life expectancy yield a potential savings of $5.3 billion dollars from a societal perspective.[25]

Despite these considerations, given the large number of ICU deaths in the US each year, it is evident that universal implementation of the Leapfrog Group's IPS Standard will save a large number of lives. Our analysis demonstrates that the majority of the avoided deaths are in the adult population but many lives will also be saved each year in pediatric ICUs. Future research should determine strategies to overcome barriers to the widespread implementation of intensivist management of ICUs.

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Table 1. Studies included in the systematic review of ICU physician staffing. The table has been modified from Pronovost et al.[1]

Source	Population	Study Design	ICUs Studied
Li et al, 1984[11]	Medical or surgical	Cohort with historical controls	1
Reynolds et al, 1988[12]	Medical (sepsis)	Cohort with historical controls	1
Brown et al, 1989[13]	Medical or surgical	Cohort with historical controls	1
Multz et al retrospective, 1998[14]	Medical	Cohort with historical controls	1
Multz et al prospective, 1998[14]	Medical	Cohort with historical controls	2
Manthous et al, 1997[15]	Medical	Cohort with historical controls	1
Carson et al, 1996[16]	Medical	Cohort with historical controls	1
Hanson et al, 1999[17]	Surgical	Cohort with concurrent controls	1
Pronovost et al, 1999[18]	Surgical (AAA repair)	Cross-sectional	39
Dimick et al, 2001[19]	Surgical (esophagectomy)	Cross-sectional	35
Dimick et al, 2002[20]	Surgical (hepatectomy)	Cross-sectional	32
Baldock et al, 2001[21]	Medical or surgical	Cohort with historical controls	1
Rosenfeld et al, 2000[22]	Surgical	Cohort with historical controls	1
Blunt et al, 2000[23]	Medical	Cohort with historical controls	1

Figure 1: Number of lives that would be saved each year by full implementation ICU physician staffing (IPS) nationwide.

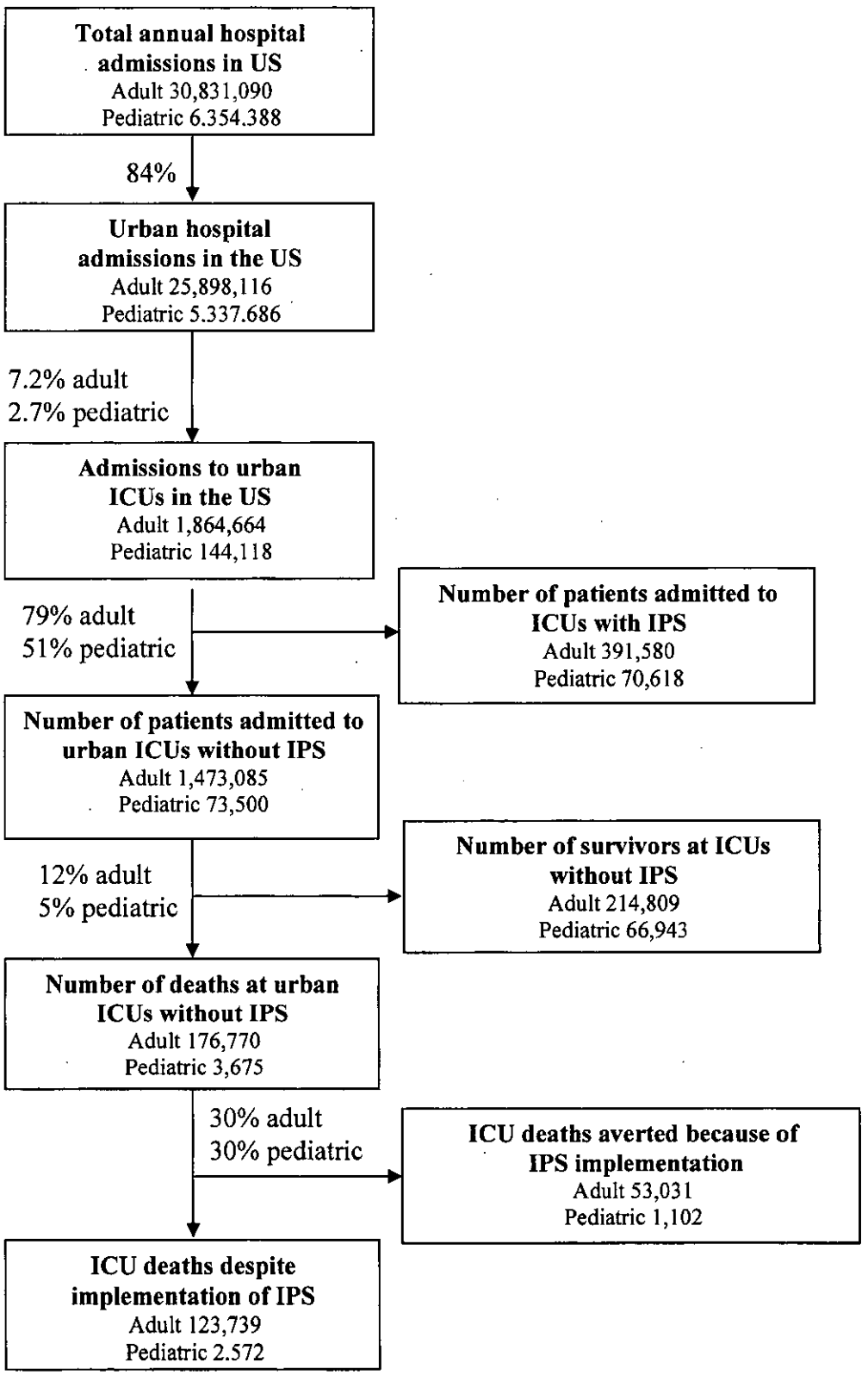


Figure 2: Mortality for high intensity vs. low intensity ICU physician Staffing. The figure has been modified from Pronovost et al.[1]

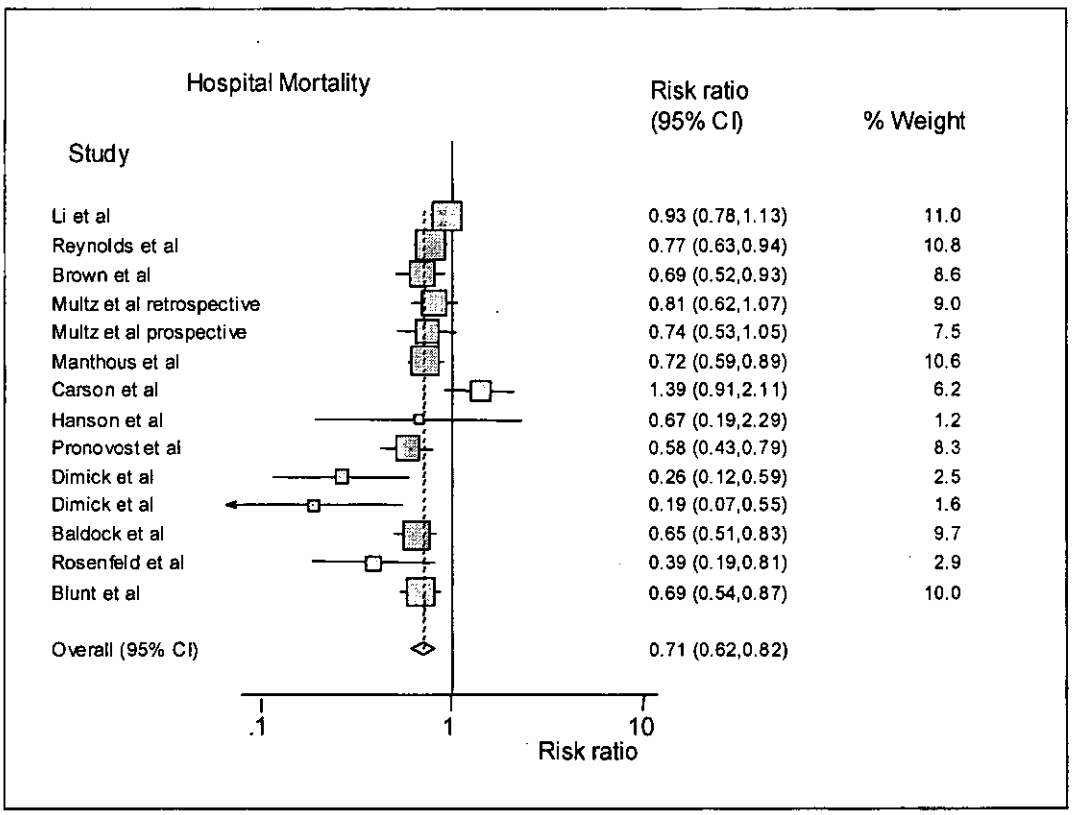


Figure 3: Sensitivity analysis demonstrating the effect of different assumptions about the effectiveness of IPS on the number of adult lives saved each year in the US.

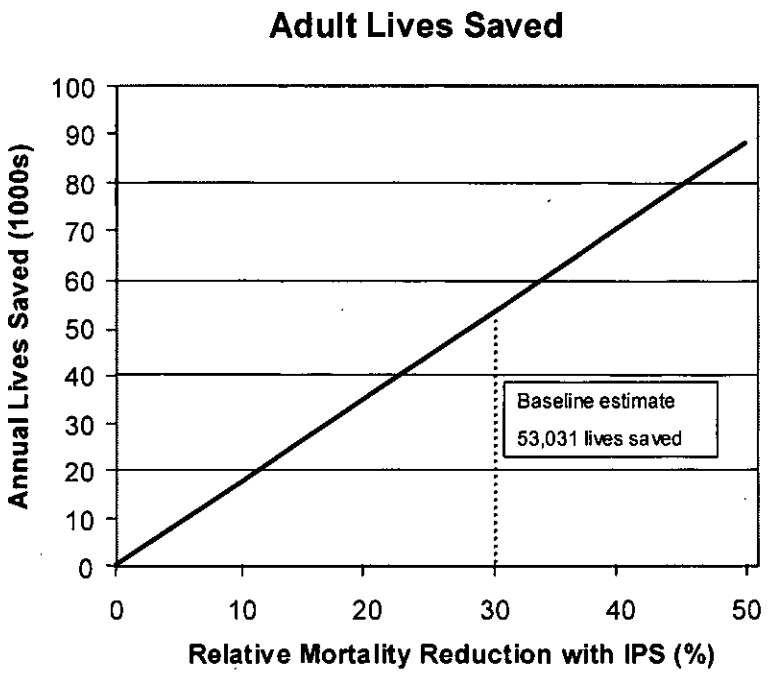
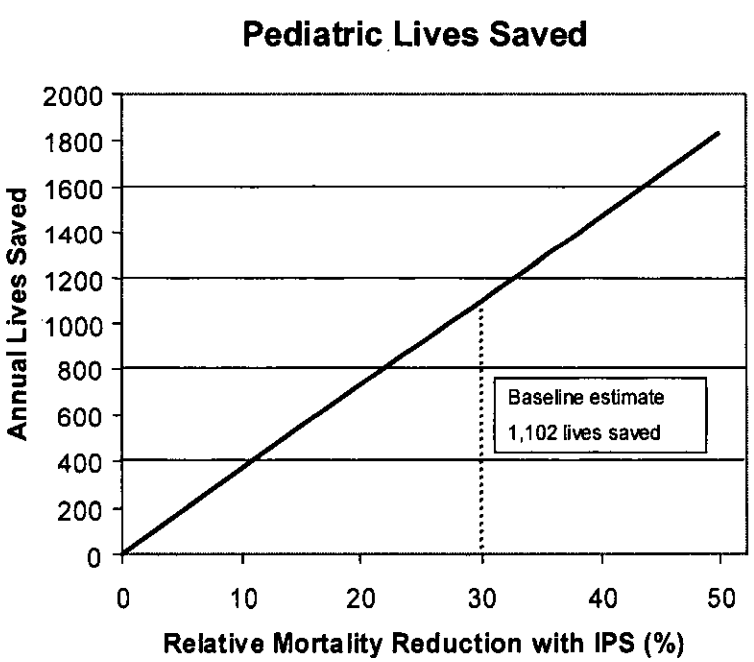


Figure 4: Sensitivity analysis demonstrating the effect of different assumptions about the effectiveness of IPS on the number of children's lives saved each year in the US.



Accelerating Change Today

A·C·T

FOR AMERICA'S HEALTH

SEPTEMBER 2002

.3.5

Care in the ICU

Teaming Up to Improve Quality

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THE NATIONAL COALITION ON HEALTH CARE
THE INSTITUTE FOR HEALTHCARE IMPROVEMENT

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Accelerating Change Today (A.C.T.)

FOR AMERICA'S HEALTH

A.C.T. is a collaborative initiative of the National Coalition on Health Care and the Institute for Healthcare Improvement. It aims to improve the quality of health care in the United States through the identification of "best practices" and administrative and clinical innovations that are: (1) yielding better patient outcomes; (2) making the delivery of care more efficient; (3) increasing access to timely medical care; (4) making the health system easier to use; (5) lowering costs, and (6) reducing medical errors and inappropriate care. The initiative seeks to accelerate the spread of best practices and innovations throughout the health system by publishing them and through presentations at medical meetings and health care and business symposia. A central purpose is to make a broad range of health care stakeholders, including consumers and those who pay the health care bill, more aware of cutting-edge efforts to improve the quality of health care. The initiative actively encourages the replication of best practices in health care facilities.

About This Publication

This report presents the stories of individuals and institutions that made a commitment to change and innovation to improve care in Intensive Care Units (ICUs). The profiles reflect some of the most promising and pioneering efforts underway in this field. The team of experts identified in the Credits and Acknowledgements developed selection criteria and determined those to be profiled. Their final choices represent the larger groups of meaningful and laudable efforts underway nationwide to improve care in ICUs.

THE NATIONAL COALITION ON HEALTH CARE

NCHC is the nation's most broadly representative alliance working to improve America's health and health care. It is comprised of 80 member organizations. They include some of the nation's largest businesses, labor unions, health care providers, consumers groups religious organizations, foundations, and health and pension funds. The Coalition was founded in 1990. It is non-profit and non-partisan. Its members are united in the belief that America needs better, more affordable health care and that all Americans should have health insurance. Former Presidents George Bush, Jimmy Carter, and Gerald R. Ford serve as the Coalition's Honorary Co-Chairs. Former Iowa Governor Robert D. Ray and former Congressman Paul G. Rogers of Florida are the Coalition's Co-Chairmen. NCHC is in Washington, DC. Founder and President Henry E. Simmons, M.D., M.P.H., F.A.C.P., is a widely respected pioneer in the field of health quality assessment and improvement.

THE INSTITUTE FOR HEALTHCARE IMPROVEMENT

IHI is an independent, non-profit education and research organization based in Boston, MA. It was founded in 1991 with the goal of fostering collaboration among health care organizations to improve the quality of health care. IHI each year holds a wide array of educational forums, symposia and workshops, and demonstration projects for medical professionals and health care administrators. IHI's co-founder and president, Donald M. Berwick, M.D., M.P.P., a practicing pediatrician and clinical professor at Harvard Medical School, is one of the nation's leading authorities on health care quality.

Accelerating Change Today

A·C·T

FOR AMERICA'S HEALTH

SEPTEMBER 2002

Care in the ICU

Profiles of individuals and institutions that have made a commitment to quality in Intensive Care Units

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THE NATIONAL COALITION ON HEALTH CARE
THE INSTITUTE FOR HEALTHCARE IMPROVEMENT

Credits and Acknowledgements

Team Leader

PETER J. PRONOVOST, M.D., PH.D.

Dr. Pronovost is an Associate Professor in the Departments of Anesthesiology/Critical Care Medicine; Surgery; and Health Policy/Management at the Johns Hopkins University. He is a practicing anesthesiologist and critical care specialist, with a doctoral degree in Clinical Investigation from the Graduate Training Program at the Johns Hopkins Bloomberg School of Public Health. His interest and expertise involve applying clinical research methods to improving quality of health care and safety, especially in intensive care units. At Johns Hopkins, Dr. Pronovost is medical director of the Johns Hopkins Center for Innovations in Quality Patient Care, co-chairs the Patient Safety Committee and directs Performance Improvement for Intensive Care Units. Nationwide, he is Chair of the ICU Advisory Panel for Quality Measures with the Joint Commission on Accreditation of Healthcare Organizations, and Chair of the National Advisory Panel for ICU physician staffing for The Leapfrog Group.

Team Member

TODD DORMAN, M.D., F.C.C.M.

Dr. Dorman is Board Certified in Internal Medicine, Anesthesiology and Critical Care Medicine. He is an Associate Professor of Anesthesiology/Critical Care Medicine; Medicine; Surgery; and Nursing at Johns Hopkins. He is the Director of the Division of Adult Critical Care Medicine, Co-Director of the Surgical Intensive Care Units, Medical Director of the Adult Postanesthesiology Care Units and Medical Director of Respiratory Care Services. He serves as Chair of the Hospital's Critical Care Committee and chairs the Continuing Medical Education Advisory Board for the Johns Hopkins School of Medicine. Dr. Dorman is actively involved in both the Society of Critical Care Medicine (SCCM) and the American Society for Critical Care Anesthesiologists (ASCCA).

Team Member

MAURENE A. HARVEY, R.N., M.P.H., C.C.R.N., F.C.C.M.

Maurene Harvey has had 36 years of critical care nursing experience. She spent the first twelve years at the bedside and is now primarily teaching. She has been a Critical Care Nurse (CCRN) since 1976, a Fellow in the American College of Critical Care Medicine since 1992, and on the governing board of the Society of Critical Care Medicine (SCCM) since 1992. She has more than 20 publications in critical care to her credit as well as one book. In 1998 she was given SCCM's NJ Shoemaker Award for Nursing Excellence and in 1999 she received the American Association of Critical-Care Nurses's Lifetime Member Award. In 2002, she became the first nurse to be president of the SCCM which is 80% physicians. She is the first nurse to serve as president of any national or international medical organization.

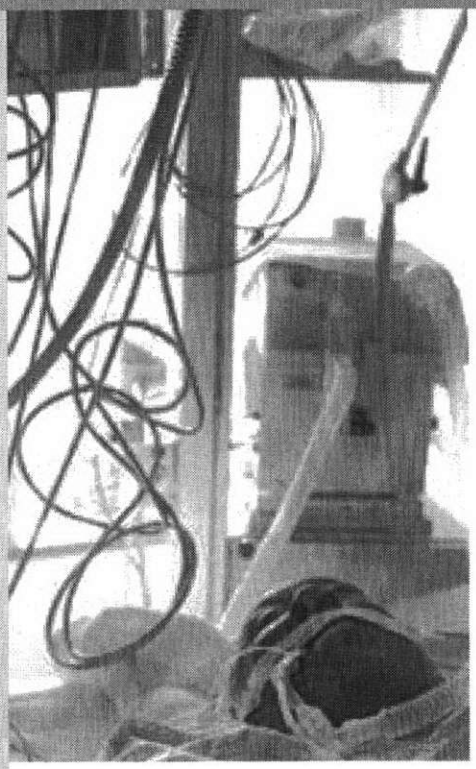
Writer

LARRY BERESFORD

Larry Beresford is an Oakland, CA-based health care journalist who specializes in the economic, policy, administrative, clinical, and human implications of care at the end of life. He is also the author of *The Hospice Handbook: A Complete Guide* (1993: Little, Brown & Co.). His articles have been published in *The Washington Post*, *Hospitals & Health Networks* and *Trustee* (American Hospital Association), *Health Plan* magazine (American Association of Health Plans), *Medicine & Health Perspectives*, *The Hospice Journal*, and a number of hospice industry trade publications. He is also a published poet and musician.

Special Photo Credit

The black and white photographs used throughout this report were taken by fine-arts photographers, **Bastienne Schmidt** and **Philippe Cheng**, as part of the Compassionate Care Photography Project at Rhode Island Hospital. The photos are on display in the Hospital's medical ICU. We wish to thank Dr. Mitchell Levy, director of the medical ICU at Rhode Island Hospital, and the photographers for allowing the use of those photos in this report.



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Support for the preparation and production of this report has been provided by The Robert Wood Johnson Foundation.

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A Passion for QUALITY

BY PETER J. PRONOVOST, M.D., PH.D.

How might America's hospitals seize the present opportunity for saving lives and costs in the Intensive Care Unit (ICU)? Jim Collins, in his book *From Good to Great*, provides some insights. For 15 years, Collins examined organizations that were average performers and then began to perform at extraordinary levels, seeking to identify factors that predicted success. One factor he identified could be illustrated by the hedgehog concept, based on the story of the fox and the hedgehog borrowed from an essay by Isaiah Berlin.

The fox is a clever, cunning animal that is kinetic and has a volatile strategic plan. The hedgehog is slow, methodological, almost homely. Although the fox tries to attack the hedgehog, the fox always goes away hungry. The hedgehog always wins because it has the ability to transform a complex world into a simple unifying concept and to steadfastly adhere to that concept: roll into a ball and stick your spikes out.

Collins recognized that great organizations and great individuals have a similar ability to transform a complex world into a simple unifying concept and then use that concept to govern all of their behavior. For Microsoft, it's software; for Starbucks, it's coffee; and for Einstein, it's relativity. For something to be a hedgehog concept, it must be (a) important, (b) something you can be great at, and (c) something you are passionate about.

A CRITICAL SETTING

For us in health care, I believe our hedgehog concept should be quality and safety of patient care. Care in the ICU, which is the most intensive, demanding, and costly enterprise in today's hospitals, meets all three requirements for safety and quality to be its hedgehog concept.

First, it is important, with over five million patients admitted annually to U.S. ICUs. Ten percent of them die during their hospitalizations, and nearly all suffer preventable adverse events. ICU care accounts for approximately 30 percent of acute hospital costs, or $180 billion annually.

Second, if we apply the available evidence, we can become great at ICU care. Currently, about 90 percent of U.S. hospitals fail to meet the physician staffing standards for ICUs that have been demonstrated to achieve the most positive and cost-effective outcomes. If those standards were implemented in all non-rural hospitals, it would prevent 54,000 deaths and save $5.4 billion annually.

THE DOCTOR-LED INTENSIVE CARE TEAM

The standards center around an intensivist physician-led, multi-professional ICU team; the same team that the Society of Critical Care Medicine (SCCM) has advocated for more than 30 years and that recent evidence shows achieves improved outcomes. SCCM has long recognized that to provide high quality care to critically ill patients, ICUs must successfully integrate the skills of physicians, nurses, pharmacists, respiratory therapists, and nutritionists, and other professionals. SCCM also recognized, and the data now support, that intensivists need to be *present* in the ICU providing timely care.

Intensivists are physicians who specialize in the care of critically ill patients. They have completed a residency in anesthesiology, medicine, pediatrics, or surgery followed by a fellowship in critical care. Many intensivists have also completed a fellowship in pulmonary medicine. My *own* research, as well as that of others, demonstrates that employing intensivists in the ICU reduces mortality and length of stay up to 30 percent, mainly because of their specialized skills in managing critically ill patients and their continuous presence on the unit to manage these medically volatile, profoundly ill patients. Yet most hospitals in the United States do not employ intensivists. In contrast, most hospitals in Europe and Australia do employ intensivists.

Intensive care is a relatively new field, and we are still learning how best to organize ICU management. That may mean a *closed* unit where the intensivist takes over primary medical management responsibility during the patient's ICU stay, or it may be more of a consultative and advisory role in an *open* unit where the patient's primary physician retains medical management, visits the patient on the unit at least daily, and remains in telephonic contact with the ICU team. Either way, the foundation of the quality ICU is the multi-professional team working in concert for the benefit of the patient.

One of the benefits of the team approach is to create a culture that is committed to quality and that allows staff to provide independent safety and quality redundancies. Specifically, the team approach creates a climate where other ICU professionals are allowed to question the physician team leader and to help ensure that patients receive the care they need – and no more.

OTHER ONGOING WORK

Several organizations and individuals have been involved in efforts to implement ICU physician staffing requirements and other standards to improve the quality and safety of care in our nation's hospitals. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is developing core quality measures that will be used in its reviews of hospitals.

VHA and the Institute for Healthcare Improvement (IHI) have a joint project underway to bring together 15 ICUs from 13 hospitals to collaborate in the design of the idealized intensive care unit. (VHA is a nationwide network of leading community-owned health care organizations and their physicians.) The project has developed measures of quality of care, a subset of which focuses on patients maintained on mechanical ventilators and key evidence-based therapeutic approaches to improve quality and survival rates for their care.

We have measured average performance in the 15 participating ICUs and estimated the opportunity to improve quality by adopting the optimal therapeutic measures for all ventilated patients – which would result in only minimal marginal costs while reducing average ICU mortality rates by 50 percent. Many of the hospitals participating in the project are now more than 90 percent compliant with providing evidence-based therapies to ventilated patients. Most started with less than 50 percent compliance.

The federal Agency Healthcare Research and Quality (AHRQ), in its report on patient safety, and the National Quality Forum both identified ICU staffing as an important opportunity to improve care. A national employer health care co-alition, known as The Leapfrog Group, is also working to improve the value and safety of health care for its employees. One area of focus is its development of new purchasing specifications for ICU care. Among those specifications are ICU staffing requirements for intensivists. We are currently working with the Group to revise the standard and to study the effect of that standard.

A FINAL HEDGEHOG TRAIT

The third and final requirement for ICU care to become the hedgehog concept for America's hospitals is the need to become passionate about the quality and safety of ICU care. In this monograph we have assembled eight stories describing 11 organizations where the passion for quality was palpable. This project, sponsored by the National Coalition on Health Care and IHI and funded by AHRQ, aims to accelerate quality improvement in ICUs by sharing the stories of ICUs that provide exceptional care. Dr. Todd Dorman, my ICU colleague at Johns Hopkins, Maurene Harvey, president of SCCM, and I set about identifying sites that had such a passion for quality, in order to produce a report that would motivate efforts to improve ICU quality and safety in other hospitals nationwide.

To identify the sites worthy of inclusion, we sent an email to SCCM members asking them to describe for us how their ICUs provide care that could take our breath away. Within a week we had received nearly 200 responses, most with supporting data. We reviewed the nominations to select the eight stories contained in this report. While their stories vary, it is clear that in each of the ICUs, safety and quality are hedgehog concepts for which the ICU team feels great passion. Furthermore, while the organizational models of the ICUs included in this monograph vary widely, they all had physician-led, multi-professional teams working to ensure that patients receive the care they needed and no more.

As you will see from the following stories, some of the sites emphasized safety engineering, borrowing quality models from aviation; or the careful tracking of quantifiable outcomes from their care; or the development of evidence-based protocols that could systematize their clinical practice. Others specialized in environmental enhancements to make the ICU a more healing setting or a more caring and skilled approach to support patients who were dying in the ICU and their families.

Actually, I should emphasize that the majority of the 11 highlighted ICUs incorporate most of the important approaches to quality. But to avoid repetition, we have opted to highlight just a few of the things that took our breath away at each site – with the understanding that they are all high-performing units in other ways, as well. In every case, their enthusiasm for quality was inspiring and infectious – often manifested in enviable staff retention rates in a field that is seriously understaffed nationally. In addition, they have hard data documenting the results of their quality initiatives.

Through this monograph we hope, like Prometheus, to ignite the reader's passion to improve safety and quality of care in the ICU. ICU care is important and we can be great at it. The question is how far are we willing to commit?

Peter J. Pronovost, M.D., Ph.D.

Associate Professor

Anesthesiology/Critical Care Medicine, Surgery and Health Policy & Management

Medical Director, Center for Innovations in Quality Patient Care

The Johns Hopkins University School of Medicine

OVER FIVE MILLION PATIENTS ARE ADMITTED ANNUALLY TO U.S. ICUs. TEN PERCENT OF THEM DIE DURING THEIR HOSPITALIZATIONS, AND NEARLY ALL SUFFER PREVENTABLE ADVERSE EVENTS.

Making a Science of Patient Safety

A SYSTEMATIC, EIGHT-STEP QUALITY PROCESS IN SURGICAL ICUs

Borrowing from aviation and other industries, a quality-improvement team strives to make patient safety a hospital-wide obsession.

Johns Hopkins University
School of Medicine
BALTIMORE, MD

How does an internationally renowned medical institution such as Johns Hopkins Hospital, with more than a century of tradition, go about germinating a new, scientifically grounded "culture of safety" within its intensive care units (ICUs)? For those involved in designing, implementing, and refining the hospital's new comprehensive patient safety program, piloted on two surgical ICUs but planned for eventual dissemination hospital-wide, the program's success starts with the leadership of safety champions and the support of the institution's administrators.

Johns Hopkins, a 1,039-bed hospital in Baltimore, MD, affiliated with the Johns Hopkins University School of Medicine, operates seven ICUs for different populations of critically ill adults. Two surgical ICUs were chosen as learning labs for the new safety program: an established, 16-bed unit and a second, with 14 beds, opened in 2000 in the hospital's new Weinberg hospital building and known as the Weinberg ICU. Both units have enjoyed enthusiastic support for piloting safety concepts from their nursing leadership and from their co-medical directors, Drs. Pam Lipsett and Todd Dorman, who set the tone and lend their authority to advancing the culture of safety. The overall ICU safety program was spearheaded by Dr. Peter Pronovost, a practicing intensivist in the Department of Anesthesiology and Critical Care Medicine at Johns Hopkins.

For these physicians, as for many other health professionals, a widely publicized 1999 report by the prestigious Institute of Medicine (IOM), *To Err is Human: Building a Safer Health System*, provided an urgent wakeup call on the need for institutional efforts to improve patient safety. But it also created an opportunity to focus the hospital's attention on an issue that had become front-page news. The IOM concluded that between 44,000 and 98,000 deaths result from preventable medical errors in the United States each year. Most of those

errors are due to problems in the systems, processes, and conditions of health care institutions rather than culpability by individual professionals.

Giving Safety a Systematic Focus

"What we did here was to recognize, first of all, that patient safety was a significant problem, and also that a systematic approach was the way to tackle it," Pronovost explains. And the ICU was a logical setting to pilot the initiative. Medical errors can and do occur in any part of the hospital but are at greater risk in ICUs given the patients' critical conditions, the intensity of their care, higher numbers of prescribed medications, and the complexities of multidisciplinary decision-making by the ICU team in consultation with the primary physician. Together, those factors add up to a higher risk for adverse events, which are defined as unexpected harms to patients attributable to their medical care.

The challenge at Johns Hopkins was how to spur an evolution from a hospital full of professionals who cared about, talked about, and tried to act on patient safety concerns in their daily routines to one that was committed to a more formal approach to safety, providing a framework or infrastructure for continuous safety improvement.

To construct such a program, Pronovost teamed up with Weinberg ICU nurse Mandy Schwartz, hospital pharmacist Bob Feroli, and Brad Weast, an administrative fellow. Together they designed a comprehensive, systems-oriented eight-step implementation process (see box at right). This informal group worked closely with the hospital's broadly representative, permanent Patient Safety Committee, with each unit's Performance Improvement Committee, and with smaller, ad-hoc planning groups formed to address specific safety concerns.

The first step in implementing the safety program was to determine prevailing attitudes about medical errors and safety issues within the hospital's culture and environment through a ten-question cultural assessment of staff on the two ICUs. Based on the responses, the safety team then set out to provide education about the emerging "science of safety" and key concepts of systematic safety engineering from other fields, such as aviation, which are now being adapted to the health care setting.

"Education is the key," Pronovost says. "People in the trenches don't think in terms of systems issues – they just see a bad event that happened. When we give our talk, at the end of it the light bulbs go on in their heads and their hands shoot up: 'Oh my God, I never thought of patient safety as a system issue, but now that you mention it, here are ten system failures that lead to errors every day.'" Once health professionals are encouraged to view adverse events as errors of the system, it becomes easier for them to identify long-standing procedural routines that might be creating hazards.

Another challenge was to persuade staff that the hospital was serious about its new "non-punitive" approach to reporting safety risks and adverse events. "We had to show them that if an error happens on their watch, they may not be the reason why it happened – it's all the policies that come together to create the event," explains Donna Prow, nurse manager of the Weinberg ICU.

Identifying the Greatest Hazards

Based on the new understanding of safety, the program's next step was to identify and then prioritize safety concerns that could be targeted for organized improvement efforts. The staffs of the two ICUs were asked to identify near misses – medical mistakes that did not lead to harm – and to predict where they thought the next medical error was most likely to occur on the unit.

An online adverse event reporting system for ICUs, developed at Johns Hopkins with a grant from the federal Agency for Healthcare Research and Quality, made it easy to nominate hazards. Identified targets for safety improvement were then analyzed, prioritized, and assigned to individuals or work teams

JOHNS HOPKINS

Comprehensive Patient Safety Program

STEP 1: Conduct a cultural survey

STEP 2: Educate staff on the science of safety

STEP 3: Identify staff's safety concerns (through a safety survey)

STEP 4: Analyze event

STEP 5: Implement improvements

STEP 6: Document results

STEP 7: Share stories and disseminate results

STEP 8: Resurvey staff – cultural survey

SOURCE: Johns Hopkins University School of Medicine, Baltimore, MD

"Education is the key. People in the trenches don't think in terms of systems issues – they just see a bad event that happened."

responsible for proposing solutions using performance improvement tools such as root-cause analysis and the PDSA (plan-do-study-act) cycle.

A key milestone in identifying safety concerns was implementing the Senior Executive Adopt a Unit program introduced in the hospital's ICUs in the fall of 2001. Each ICU has been adopted by a senior hospital administrator (university president, dean/CEO, hospital president, chief operating officer, or vice president), who visits the unit monthly for a candid, confidential, on-site discussion with staff about their safety concerns and their ideas for how to solve them.

The first cultural survey had discovered that while staff members believed their managers and clinical leaders at the unit level cared about patient safety, they were not as convinced about the commitment of senior administrators. When the survey results were shared with administrators, they agreed to implement the Adopt a Unit initiative. Their regular appearances on the units demonstrate the institution's commitment to safety while their reports back demonstrate its responsiveness to staff safety suggestions.

On a recent Thursday afternoon, the hospital's COO, Judy Reitz, ScD, is in a conference room with a half-dozen nurses and other team members from the surgical ICU, following up on issues identified the previous month during her safety rounds on the unit. "Our agenda is to focus the organization and all of its constituent groups around the issue of safety," Reitz tells the nurses. "What I can contribute is connecting the dots" within the hospital, making sure that responsibility is assigned for safety projects and that actions are reported back to the unit.

A suggestion made at the previous meeting, which Reitz had helped to implement, was to create a specialized patient transport team in the hospital to deliver patients to medical appointments throughout the facility. However, analysis of the program's first month of operations indicates that there still are bugs to work out. Having an assigned transport team is no guarantee that it will be available when the ICU team requests it. Reitz discusses with the nurses what would be a reasonable target rate of availability and how requests for the team's services might be prioritized based on medical acuity.

Targeting Communication Breakdowns

Two other ICU safety initiatives at Johns Hopkins are the Daily Goals and Objectives Sheet and the medication reconciliation process. As in many hospitals, the ICU team conducts daily morning rounds on every patient. The multidisciplinary team, including the attending intensivist on duty, medical fellows and residents, the patient's nurse, nurse specialists, and other professionals, moves from room to room, thoroughly discussing each patient's condition, progress, and goals for medical management – while teaching the residents and fellows on the job. Supporting the discussion at the bedside are the computerized medical chart displayed in each patient's room and the banks of high-technology vital sign-monitoring equipment.

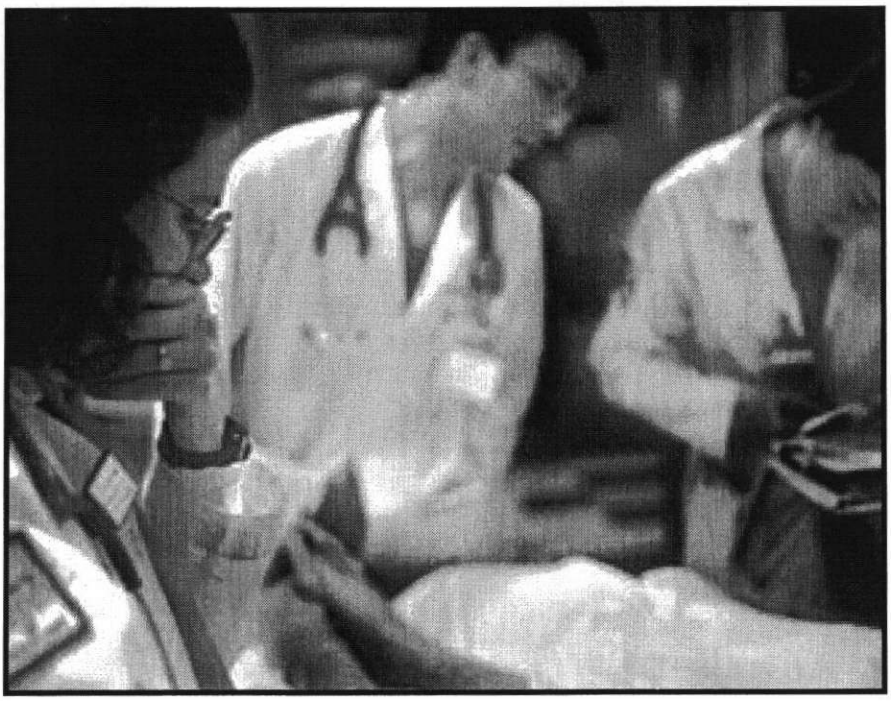
However, communication was not always as clear as it needed to be between the rounding team and the nurse – who spends the most time at the patient's bedside but may be called away by other pressing patient needs. In response to communication breakdowns, the safety team proposed the handwritten Daily Goals and Objectives Sheet, which is handled separately from the permanent medical record containing physician orders and other pertinent charting data.

The daily goals sheet can be quickly filled out by a resident during rounds, triggering key questions that otherwise might get overlooked – even such basic questions as why is this patient in the ICU and what are the greatest current safety risks. It is left at the patient's bedside as a reminder of the priorities for the day and revisited throughout the day by physicians, nurses, and respiratory therapists to see if the goals for the patient's medical management are being met.

The goals sheet also engineers independent safety redundancies into the ICU care process. For example, protocols recommend five therapies every day for patients on mechanical ventilation: elevating the head of their bed, preventive treatment of peptic ulcer and of deep venous thrombosis, a trial of cutting back on sedation, and an attempt to wean the patient from the ventilator. By providing an independent reminder of these therapies to staff, physicians, and families, the goals sheet has helped the units achieve 90 percent-plus compliance with the vent protocols and contributed to an overall reduction in ICU length of stay down to an impressive 1.05 days.

The drug reconciliation process grew out of recognition that the point of discharge from the ICU exposed patients to the greatest danger for medication errors – including incorrect dosages, essential prescriptions from before the ICU stay left off the post-discharge care plan, continuation of medications started in the ICU that are no longer needed or appropriate, drug allergies, and risks for poly-pharmacy interactions. A review of 30 charts confirmed the high incidence of such errors at the time of ICU discharge.

Drug reconciliation creates an independent redundancy to help prevent medical errors. A staff nurse completes the standardized form immediately before discharge and confirms allergies



and home medications with the patient. Any questions or discrepancies need to be resolved with the medical fellow on the unit or the patient's primary physician. Just by implementing this process for every patient, medical errors at the time of discharge have been reduced to nearly zero.

Speaking Up for Patient Safety

"We have actually created a culture where anyone on the team is allowed to second-guess the doctors," Pronovost says. If a nurse on the unit believes that a resident is about to make a medical error, that nurse is encouraged – and even expected – to go over the resident's head to the medical fellow and from there to the attending physician until the question is resolved, Dorman adds. And that message, clearly supported by the co-medical directors, radiates from the top down throughout the unit.

Ad hoc ICU quality teams also have studied clinical issues such as nurse-to-patient ratios, the need for standardized intravenous medication preparations, and bloodstream infections in patients who have implanted, central-line catheters. For the latter, the medical literature was reviewed to identify the latest information on sterile techniques. Staff was then trained in optimal techniques of full-barrier precautions, but infection rates on the units did not go down as much as the safety team hoped.

The team then observed and talked with staff, discovering that while all of the supplies and equipment needed for optimal sterile technique could be found on the unit, they were stored in different locations. Since that unintended system feature made it harder for nurses to round up all of the supplies when they needed them, it was easier at times to cut corners on technique. The solution: a rolling "line cart" that has all of the supplies readily accessible in a single mobile location.

In all, the surgical ICU now routinely collects data on 19 other quality indicators for which medical research suggests important links to overall quality of care. They range from regularly assessing the level of patients' pain to confirming the use of medically indicated prophylactic therapies. Dr. Sean Berenholz of Johns Hopkins University's medical faculty worked with Pronovost to develop a standardized data collection tool, trying to balance the need for quality and outcomes data with minimizing the burdens of collecting them.

Weinberg ICU is now piloting the use of an electronic writing recognition pad for gathering the 19 quality indicators. Nurses can quickly check off boxes on a specialized data form on the electronic pad, which transmits the information to a palm-held computer for eventual uploading to the data base. The data collection process is constantly undergoing streamlining and revision, while the results are analyzed and brought back to staff for review on a monthly basis – creating fresh motivation to keep generating the data. "We really try to incorporate safety into our daily practice, but to improve, we have to be able to measure what we're doing," Berenholz explains.

Documenting the Results

For all of the specific safety activities initiated through the comprehensive safety program at Johns Hopkins, it is necessary to document their outcomes: Did the measures achieve the desired result? Is further exploration needed? Were there unintended consequences? "We've had minimal resistance to our safety initiatives in the hospital, because we had the administration's support and because we've really tried to do management by data," Pronovost says.

Administrative fellow Brad Weast compares the process of hospital safety engineering to contemporary automobile plants where any worker on the assembly line can push a button and make it stop until the team addresses a potential safety or quality concern. While it is not possible to stop the assembly line in the ICU, staff can take the time to analyze complex care processes and break them down to their individual components, looking for opportunities to streamline the process and engineer out potential hazards.

The final step in the safety program's eight-stage process was to repeat the cultural survey used in Step 1, to see how much had really changed in the overall culture of the ICUs at Johns Hopkins. Results of the repeated survey confirm the staff's perceptions of an improved culture of safety. "We knew a culture of safety was important but we did not know if we could change it," Pronovost says. But the results demonstrate measurable improvements and reduced errors – all achieved in just six months. ■

Decreasing Costs by Improving CARE

DATA-DRIVEN QUALITY IMPROVEMENT PROGRAMS IN THREE ICUs

Following divergent paths, intensive care units in three community teaching hospitals have established strikingly similar, medical evidence-based quality initiatives.

St. Vincent Hospital
WORCESTER, MA

Stamford Hospital
STAMFORD, CT

St. John Medical Center
TULSA, OK

The Department of Critical Care Medicine at **St. Vincent Hospital**, a 300-bed community teaching hospital in Worcester, MA, laid the foundation for its culture of measuring outcomes to steadily improve the quality of care by first becoming "absolutely fanatical about data," reports department chief Dr. David Kaufman. The department was formed in 1989, but initially it had limited authority and faced some skepticism from the hospital's medical staff. "It was clear that if we wanted to grow this department, we would have to justify it with data. It is tremendously important for us to produce the best possible outcomes from our care, and the only way to know that is to measure them."

In working with the hospital's information technology staff to build a homegrown, comprehensive ICU database, Kaufman was asked what kind of data he wanted to collect. "I said we needed to collect everything. They asked what questions we needed answered, but we didn't know that yet. As the database grew, new questions emerged. Now we have eight years of data and we're going back to mine the data."

For the medical/surgical/coronary ICU at **Stamford Hospital** in Stamford, CT, a similar commitment to evidence-based medicine and data-driven quality improvement emerged as critical care was being reorganized in the context of an impending hospital merger. The unit's director, Dr. James Krinsley, was inspired by an ICU management course taught by Dr. Terry Clemmer, whose widely admired, protocol-intensive ICU program at LDS Hospital in Salt Lake City, UT, is profiled in the next section of this report. But the 305-bed hospital and its sophisticated medical staff were already primed for such an approach, Krinsley says. "Basically, at this hospital, when a good idea is generated, you just run with it."

Similar changes were brewing at 720-bed **St. John Medical Center**, a community teaching hospital in Tulsa, OK. In 1995 the hospital launched a physician credentialing policy for its ICUs and a critical care rotation for medical residents

from the University of Oklahoma. But the new Adult Critical Care Department and its data-driven approach received their biggest boost from a field trip to tour an established, outcomes- and protocol-intensive critical care program at Phoebe Putney Hospital in Albany, GA.

Dr. Gerald Plost, the department's director, organized the two-day trip at the invitation of a colleague, Dr. William Brock at Phoebe Putney, and led a team of 11 observers, including representatives of key physician groups at St. John and members of the ICU interdisciplinary team. They studied the practice of critical care at the Georgia hospital, including its medical rounds and care planning, and learned from its impressive results in such areas as safety management, clinical outcomes, and cost containment. This first-hand exposure and the excitement it generated helped to secure buy-in for implementing similar concepts at St. John.

COMMON ELEMENTS OF QUALITY IMPROVEMENT

Following different paths and operating under different models of unit management, the three community teaching hospitals in Worcester, Stamford, and Tulsa have instituted strikingly similar ICU quality improvement initiatives that share many key elements. All three started with a commitment to data-driven quality improvement for their ICUs, championed by their medical directors in close collaboration with nursing leaders and with the explicit support of the hospitals' administrators.

All three built sophisticated computerized databases to track and compile a variety of outcomes from their clinical care. Each also enrolled in Project Impact, a national ICU database established in 1996 by the Society of Critical Care Medicine, in order to benchmark and compare its performance with other ICUs. More than 120 hospital ICUs now submit consistently collected data to Project Impact and receive regular statistical reports comparing their outcomes with peer groups of similar ICUs around the country.

The three critical care departments developed standardized care protocols for many of the fundamental quality issues in intensive care, based on the best current evidence in the medical literature, reviewed and adapted by quality improvement teams within their institutions. Such protocols address ventilator management and weaning, extubation and the avoidance of unplanned reintubations, prevention of infections, central line insertion and maintenance, prevention of deep vein thrombosis, sedation, even pain management and skin care. The protocols have been refined based on experience on the units and tested against outcomes data from the departments' comprehensive databases in a continuous cycle of testing, evaluation, and improvement. Safety management, described in the first profile in this report, is also emphasized.

Together, these activities have resulted in dramatic improvements in key outcomes of care on the ICUs as well as significant advances in cost containment at each hospital. The units receive high marks from their hospital administrators, who have tried to adapt their lessons to other departments. Their experience also underscores the opportunities for other community hospitals to institute similarly sophisticated, comprehensive, multidisciplinary, intensivist-led, evidence-based, data-driven, cost-effective approaches to quality improvement.

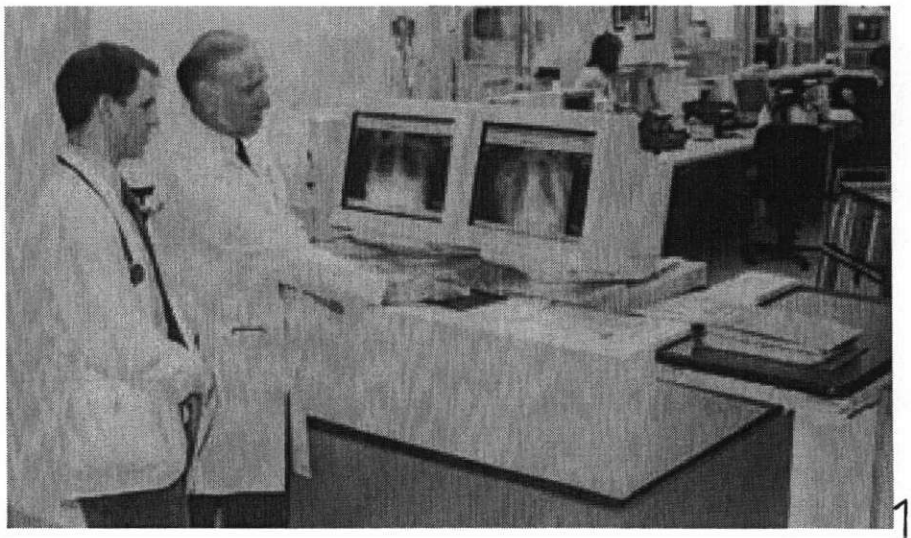
"A lot of people assume that this kind of approach is just for the large academic medical centers, but in our area, we're actually ahead of some of the academic centers," Plost notes. "But you can get there quite rapidly if you go about it in the right way."

AN IDEA FOR A HIGH-PERFORMING ICU

The Adult Critical Care Department at St. John in Tulsa is comprised of three units: a 15-bed surgical, a 10-bed medical, and a 10-bed coronary ICU. The quality improvement process implemented in the department over the past two years had its roots in Plost's attendance at national critical care meetings and his idea that "we could achieve better results.... All hospitals do quality monitoring, but we wanted to do more than that – and really emphasize the quality of the data." In 2000, Plost brought his idea to the hospital's administration and medical management committees. They asked for evidence that this approach could actually produce such results.

Evidence supplied by Phoebe Putney Hospital was enough to convince the hospital. After Plost's ICU group returned

Dr. David Kaufman of the Department of Critical Care Medicine at St. Vincent Hospital with a medical student. *(Photo courtesy of St. Vincent Hospital)*



The Adult Critical Care team at Stamford Hospital includes (from left to right) James Krinsley, M.D., Director of Critical Care; Valerie Neary, R.N., Nursing Director of Critical Care Services; Santi Neuberger, M.D., Department of Internal Medicine; Joan Grande, R.N., Charge Nurse, Critical Care Unit; Ruby Beverly, Unit Coordinator, Critical Care Unit. *(Photo courtesy of Stamford Hospital)*

from its field trip to Georgia, he formed a small ICU management team with nursing leaders from the units and a data analyst, augmented as needed with other expertise from hospital and medical staff. Given clear lines of authority and accountability by the hospital, the team began meeting once or twice a week to start implementing real change aimed at defining, measuring, and tracking performance on the units. "Our goals included a commitment to a process of continual improvement and decreasing costs while improving quality," Plost relates.

The group also set to work drafting, testing, and implementing 18 care protocols in its first year. Each protocol was reviewed by the relevant hospital committee on a fast track for approval. Each was built on established medical evidence and what was already being done at other hospitals and each was written with the goal of keeping it simple and easy to follow. Some of the protocols are "opt in" – meaning the physician specifically writes the order to use them, and others are "opt out" – meaning the physician must specify when the protocol is not to be followed.

"At the same time this was going on, we also needed to see how we were doing (on overall performance)," Plost notes. With results generated from the department's computerized outcomes database, "we could track all three units' performance on graphs, and they started improving dramatically right away. Slowly but surely, the culture of care in the ICUs began to change. In an important early victory, we shaved an average of two days from the length of time patients spent on ventilators in the medical ICU, resulting in $1 million in annual savings for the hospital." Lengths of stay on the units and the proportion of patients discharged alive are all higher than matched, severity adjusted comparison groups from the Project Impact national database.

In year two the ICU management group took aim at more subtle outcomes, including patient/family satisfaction. Year three and four targets will include specific medical problem areas such as renal failure, more complex disease management protocols, and protocols for a new trauma service, as well as offering input on redesign of the physical environment for the units. Meanwhile, existing protocols will be revised as needed, based on the emergence of new medical evidence, so that they continue to reflect best current practice.

INCENTIVES TO SUPPORT THE PROTOCOLS

Recently, the ICU management team at St. John decided to take a closer look at compliance with its clinical protocols and found that they were being followed correctly about 70 percent of the time in situations where they could have been used. "I wanted to get the compliance rate up to 90 percent, so I went to every department in the hospital and gave a one-hour talk about the protocols," Plost says. But when compliance did not improve, it became clear that education alone was not enough. So the team came up with an incentive program for nurses on the units, since they are in the best position to educate physicians about the protocols and their benefits for standardizing quality.

After providing the nurses with training in how to present the protocols to attending physicians, the team enhanced their motivation by offering rewards for raising compliance rates to 90 percent. The incentives, funded by a private donor, included new equipment, a party for all unit staff, and a drawing for three expense-paid trips to a critical care conference in Las Vegas, NV. Within three months they had achieved a compliance rate of more than 90 percent.

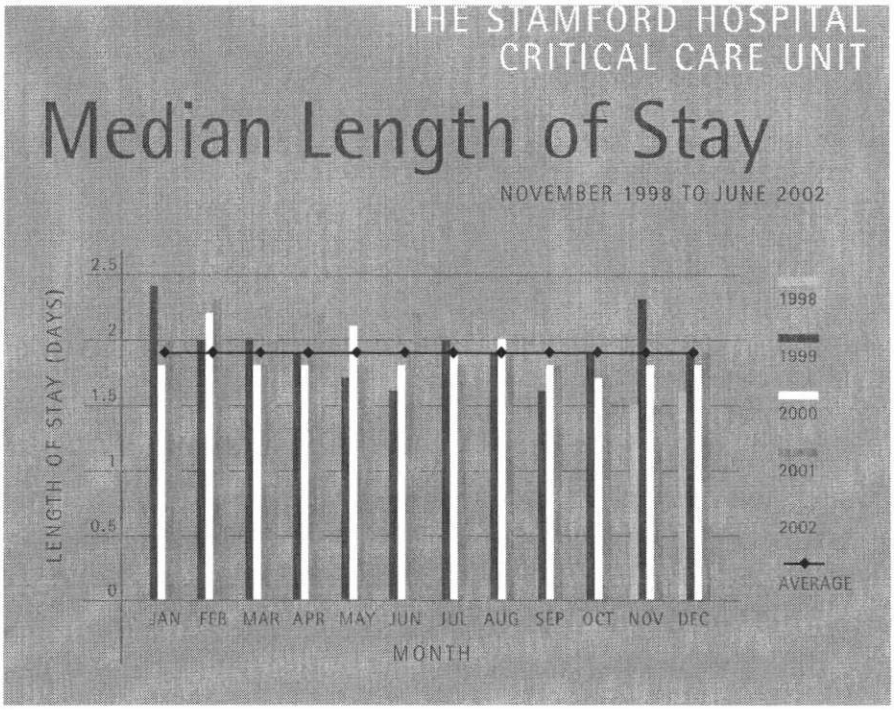
The leadership of a physician champion who is inclusive and team-oriented has been essential to the program's success, notes St. John senior vice president Howard Peterson. "Dr. Plost involved the board early on, and he keeps the administration informed of the cost and outcomes measures," demonstrating the correlations between cost reduction, quality improvement, and patient satisfaction. "And on top of that, our employee satisfaction is much higher," reflecting the staff's appreciation for more streamlined care protocols leading to better patient outcomes, Peterson says.

Nurses on the unit seem pleased with the emphasis on protocols, says Kathy Staggs, nurse and clinical director of critical care at St. John. "The more they use them, the more they see, 'When I use the protocol, everything runs like clockwork.' That's when you can see the lights start to go on. Now they're coming up with ideas of their own," such as a family support protocol.

RIGOROUS OUTCOMES ANALYSIS AT STAMFORD

Like the ICUs at St. John, the 14-bed mixed adult ICU at Stamford Hospital uses an open management structure, in which primary physicians retain care management responsibility while the Director of Critical Care is responsible for general oversight and supervision, education, protocol development, and data analysis. The part-time position of director was created in 1998, and Dr. James Krinsley was hired to fill it.

Krinsley quickly set out to implement a performance improvement initia-



The median Length of Stay is one of many indicators that hospitals need to track in order to assure high quality care in ICUs.

tive built on rigorous outcomes assessment and the monitoring of adherence to protocols established for the unit. "We created a culture of protocols and intensive outcomes analysis – a data-intensive, data-conscious culture," Krinsley relates. "I'm the data guy. I've always loved numbers. When I started out, I didn't know how to use computerized spreadsheets. But I learned and built the program piece by piece," he says.

"For the first couple of years, I was collecting the data on my own. I wanted to make sure that it was done right. Now I have help from the hospital's information technology department." The current master ICU database includes diagnoses, severity-of-illness scores, length of stay measured in 0.1 day increments, co-morbidities and other demographic data, ICU outcomes, and a detailed ventilator database. Computerized queries link individual radiology, pharmacy, and laboratory charges, laboratory values, and final ICD-9 discharge codes to the ICU database, facilitating a rich array of detailed outcomes analyses.

Krinsley regularly covers the walls of the ICU conference room with his colorful charts summarizing the outcomes data, and he is preparing several manuscripts on the data for publication. The charts tell the story of advances in quality, including steady reductions in rates of central line infections, ventilator-associated pneumonia, and reintubations.

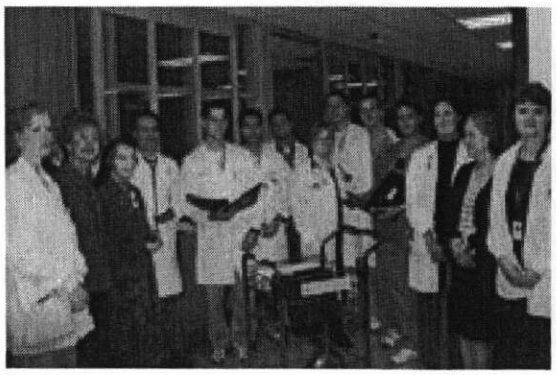
Krinsley notes that he was fortunate to be given a free hand by the hospital's administration to implement his quality concepts. He also enjoys a close working relationship with the ICU nurse manager, Valerie Neary, who says, "This is a real team effort – not just medicine. It's an interdisciplinary group of people that comes together to write the protocols," also including respiratory therapists, pharmacists, and a clinical dietician. "What we emphasize is how we listen to each other, and how to work together so that we all have ownership in the process. That's part of the cultural change," she says.

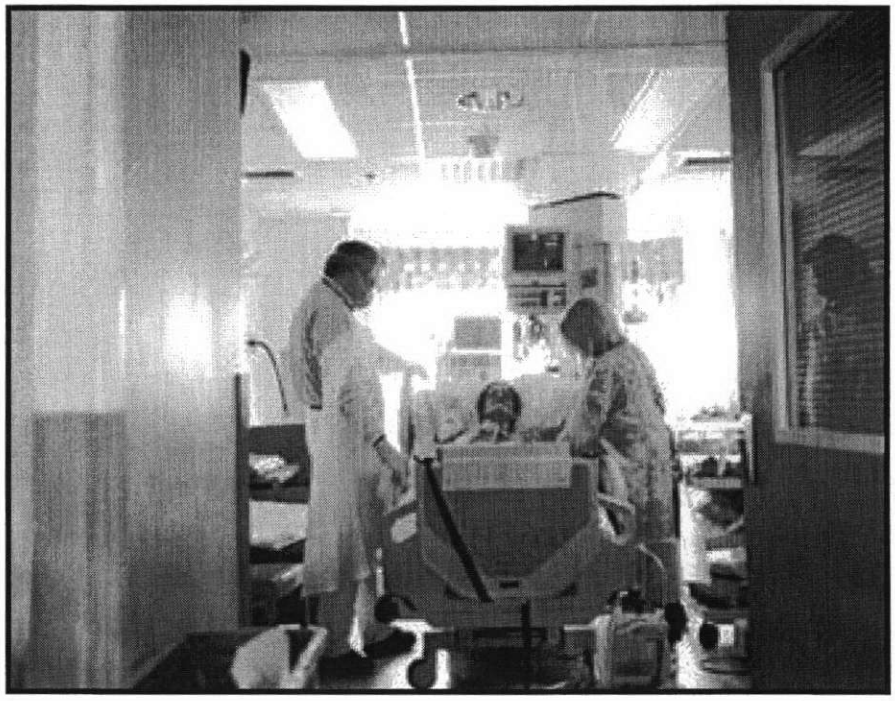
A major target for the new department's quality initiative was to develop a protocol for enteral nutrition for critically ill patients – which is typically done with a feeding tube through the nose into the stomach. The four-part protocol, developed by a multidisciplinary quality team, specifies when enteral feeding is indicated or contraindicated, when to use an enteral feeding formula that includes fiber or immune-enhancing supplements, and how to prevent diarrhea, which is a common side-effect.

Another recent quality initiative studied the ordering of portable chest X-rays on the unit, which were costing nearly $1 million per year. "Residents often order studies without considering whether the result will affect any outcome," Krinsley says. In March 2001 the department adopted a protocol requiring house staff to fill out a form stating the reason for ordering a chest X-ray. Utilization went down 28 percent over the next 12 months, generating savings of $173,499 without affecting ICU length of stay, survival, or duration of mechanical ventilation. "We plan to apply a similar process to drug utilization patterns in the ICU, particularly regarding four high-cost antibiotics that can often be given enterally rather than by the more expensive intravenous route."

The ICU's protocols and outcomes monitoring reflect an overall institutional approach to quality and clinical effectiveness at Stamford Hospital, says Dr. Michael Parry, the hospital's vice president and chief medical officer. "But clearly, Dr. Krinsley has taken that ball and run with it. He is more involved than any other physician on staff, and his development of protocols has been a model for the rest of the hospital."

The SMJC Interdisciplinary Team in the ICU. *(Photo courtesy of St. John Medical Center)*





COST IS AN IMPORTANT OUTCOME

The freestanding Department of Critical Care Medicine at St. Vincent Hospital in Worcester includes seven physician intensivist members who have varied primary medical specialties, led by director Dr. David Kaufman. The combined, 38-bed Critical Care Center, which moved into a beautiful new hospital building in 2000, intermingles a medical and a surgical unit.

Established in 1989, the department slowly established credibility within the hospital and essentially became a closed unit in 1998, with the unit's critical care specialists assuming responsibility for managing the medical care of patients on the unit. But it retains a collaborative orientation to its primary "customers": primary care physicians and surgeons. Their satisfaction is regularly measured and has improved steadily in recent years.

"The culture of evidence-based medicine is what we have lived here. We try to give it as much substance as possible," through the involvement of the multidisciplinary team and ongoing direction from the Performance Improvement Committee, Kaufman says. In addition to demographic, clinical, service, outcomes, pre-admission, and post-discharge data, the ICU databases incorporate the costs of care as another essential aspect of outcomes and quality.

That is not just because it is fiscally responsible – given that the ICU is the most labor-intensive, intervention-heavy, and expensive area of the hospital, with typical costs per day running three times as high as general acute hospital wards. Providing high-quality intensive care and thereby minimizing infections and other complications can also reduce costs and length of stay on the unit – which is good for everyone, Kaufman notes. Complications are hugely expensive and harmful to ICU patients, while just being in the ICU carries its own risks, such as nosocomial infections. Managing intensive care effectively and efficiently also requires managing admissions – only admitting patients who need that intensity of care and who can be expected to benefit from it – and planning up front for appropriate discharges.

"I'm intensely concerned about saving money, because I believe providing good care at the right time is cheaper," he explains. Avoiding medical interventions that are not substantiated by evidence-based medicine helps to prevent waste of precious medical resources and may protect patients from unnecessary risk.

OUTCOMES MANAGEMENT IN PRACTICE

The ICU Performance Improvement Committee at St. Vincent developed a protocol to control the utilization of propofol, an effective but expensive sedative. By requiring the approval of a department intensivist to order propofol, the team saved $105,808 in 2001 compared with two years before. The committee also looked at reducing other unnecessary lab and X-ray testing through the development of protocols and intensivist-led oversight.

Another example of the unit's quality management, illustrating the problem-solving process and dogged pursuit of better outcomes, is the incidence of ventilator-associated pneumonia (VAP) – which can be catastrophically life-threatening for ICU patients. The database showed that ICU patients had an unacceptably high rate of VAP, confirmed by the hospital's participation in the Maryland Indicator Project, which benchmarks ICU data from multiple hospitals. But the ICU team didn't understand why the VAP rate was so high on the unit. "We put together a group of intensivists, respiratory therapists, nurses, and an infectious disease physician. We looked at how often our tubing was changed, suctioning, anything we could think of," Kaufman relates.

"We decided to try two things. First, would it help if we raised the head of the bed for every patient on a ventilator to an elevation of 30 to 45 degrees? Second, our patients on ventilators who were on feeding tubes typically had the tube through their nose. When the tube goes through the nose, it may obstruct the opening to the sinuses. So we said, for all patients on ventilators, unless there's a reason to have the tube through the nose, let's use an oral gastric tube instead. And the results speak for themselves." From rates of 14 to 22 incidents per 1,000 patient days on ventilators on the unit prior to implementing the new protocol in 1997, the incidence of VAP was down to just one per 1,000 vent days by 1999.

And thus the continuous cycle of improving quality of care in the ICU leads to the more efficient use of finite health care resources – and better results for the critically ill patients. ■

Refining the ART OF PROTOCOLS

EXPERIENCE, COMMITMENT TO COLLABORATION LEAD TO MORE SOPHISTICATED PROTOCOLS

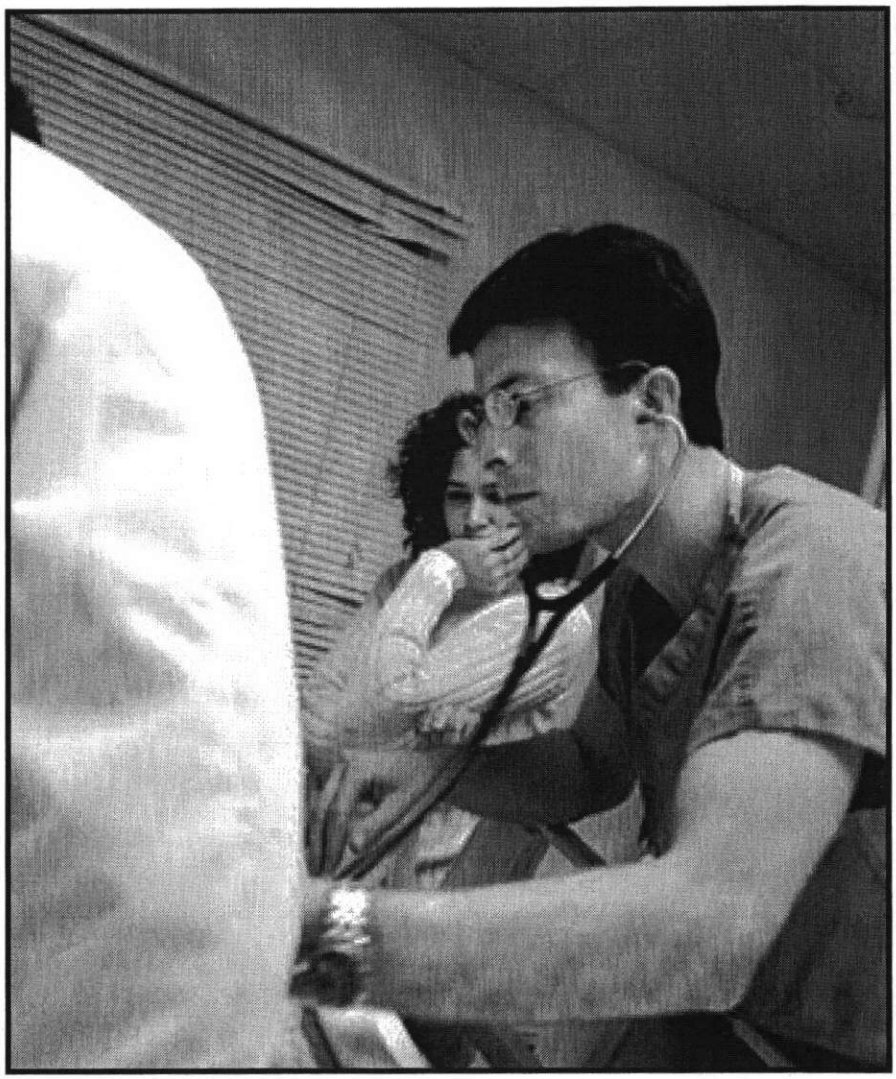
One ICU's painstaking quality improvement process builds relationships, teamwork, and the staff's personal ownership of clinical protocols.

The Shock Trauma Respiratory Intensive Care Unit (STRICU) at LDS Hospital in Salt Lake City, UT, has worked long and hard on its process of developing protocols, which are policies spelling out standardized, optimal departmental practice in given clinical situations, says the hospital's director of critical care medicine, Dr. Terry Clemmer. Along the way, the STRICU team has learned important lessons about how protocols could be more effective tools for improving the quality of intensive care – thereby making an expert ICU team even better, utilizing its resources more effectively, and saving lives.

First of all, the current set of 19 clinical protocols is subject to frequent revisions in response to new developments in medical research and actual experience on the unit. If a protocol doesn't work in practice – and new ones crafted by committee are rarely written in a form that is ready to work well on the ICU floor – then the team that drafted it is responsible for refining and making it more effective. Another key is to monitor ongoing compliance with protocols – and their results in terms of clinical outcomes.

Personal buy-in for accepting and using the protocols by STRICU staff and by the physicians who place their critically ill patients on the unit is essential. In fact, Clemmer says, the relationships, trust, and collaborative teamwork developed through the process of crafting the protocols ultimately are more important than what is on the piece of paper.

LDS Hospital
SALT LAKE CITY, UT



A TRADITION OF QUALITY IMPROVEMENT

The 12-bed STRICU at LDS Hospital has been celebrated for its quality improvement processes, including its advanced use of protocols. The unit's staff serves as faculty for ICU training courses at the Institute for Healthcare Improvement and elsewhere and participates in national research activities. The unit produces exceptional outcomes in such areas as acute respiratory failure and trauma while steadily reducing costs and average length of stay, Clemmer notes.

In developing its quality program, the STRICU enjoyed several built-in advantages. First of all, 520-bed LDS Hospital pioneered the development of computerized medical records and hospital information management in the mid-1960s, and its sophisticated clinical information system facilitates outcomes data retrieval and the use of decision support tools. Clemmer has directed the critical care program since 1976, and many staff nurses also have lengthy tenures.

The hospital's parent system, 22-hospital Intermountain Health Care (IHC), has been recognized for its quality improvement activities and is home to quality expert Dr. Brent James, a protégé of legendary industrial-model, quality improvement guru Edward Deming. The roots of the STRICU's commitment to transform its clinical practice and create an environment that supports practice improvement lie in the participation by Clemmer and then-nurse manager Vicki Spuhler in a 1992 training course taught by James, "The Advanced Quality Improvement Program."

The unit was already working on protocol development, Clemmer relates, "but the course really solidified our ideas." With its inspiration, they brought unit staff together for a one-day, off-site retreat to discuss where they wanted the unit to be in five years. Standardization of practice was identified as the way to achieve the vision. "We got really turned on to the idea that this could be applied in the ICU." The first protocol development team was launched the following year.

BIRTH OF A PROTOCOL

How do the clinical protocols used on the STRICU come into being? Clemmer outlines a process that is more complicated than some of the other quality improvement programs described in this report. But if that process wasn't honored, he says, the protocols would lose much of their transformative power.

Ideas for new protocols are generated by front-line professionals on the unit, especially the nurses. Often they felt frustrated by the wide variation in critical

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"BY THE TIME WE'VE MADE THE PROTOCOL FUNCTIONAL... THE FRONT-LINE TEAM HAS LEARNED NEW PROBLEM-SOLVING SKILLS."

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care practices of the 55 attending physicians who admit patients to the unit, the five members of the academic critical care faculty group that manages it, and the six private critical care physicians who participate in staffing the unit's 24-hour, on-site intensivist coverage. The STRICU's Quality Improvement Coordinating Council, which meets monthly, assigns clinical issues for protocol development to smaller multidisciplinary teams of five or six members.

The smaller, ad hoc group hammers out a first draft of a proposed protocol around a conference table, armed with the best current medical evidence from a thorough review of the literature. Since there is no solid, controlled trial research evidence to answer many of the clinical questions that arise in intensive care, the group often must fall back on its collective experience working on the unit.

In fact, says STRICU intensivist Dr. Jim Orme, some of those meetings have led to shouting matches over strongly held differences of opinion. A lot of painstaking discussion goes into making sure that every point of view is considered and reconciled. Over time, Orme says, as participants have grown more confident in the process, the effectiveness of protocols, and the ability to improve them based on actual practice, the level of argument has subsided.

Clemmer sends the first draft of a new protocol to ICU staff and to the 55 referring physicians for their review and input, so that they will feel ownership and buy-in when it is eventually implemented. The feedback is incorporated and, if necessary, he will negotiate one-on-one with doctors who have strong conflicting views. "If they don't like it, we need to work on it. Otherwise, they won't use it," he explains. Typically, a protocol goes through three or four iterations before it is ready to test on an actual patient on the unit.

"You can't understand in the conference room how it will work in the clinical environment," Clemmer says. "So we immediately start to revise. By the time we've made the protocol functional for the clinical environment, it's already working. Even more importantly, the front-line team has learned new problem-solving skills," he says. "But you really need an open environment where people feel comfortable bringing up issues. Staff members constantly ask questions to make care processes safer."

GENERAL GUIDELINES FOR

PROTOCOL APPLICATIONS

Protocols are a method of standardizing the care of patients in the STRICU. They lay a foundation which allows us to better evaluate care and discover methods to enhance its quality. *They do not constitute the only acceptable approach to care.* Deviations from the protocols should not be viewed as inappropriate care but as a different idea which might be useful to improve the protocol decision making rules.

In order to meet our goals of improving care, the following guidelines are strongly encouraged with respect to the use of protocols:

1 ■ Whenever the protocols fit the clinical situation their use is strongly encouraged.

2 ■ Protocols should never be followed blindly without scrutiny and question as they may not always be appropriate for every clinical situation.

3 ■ Overriding the protocols constitutes an opportunity to discover how they might be improved. Therefore, the reasons for overrides need to be documented and evaluated so the protocol can make better decisions in the future.

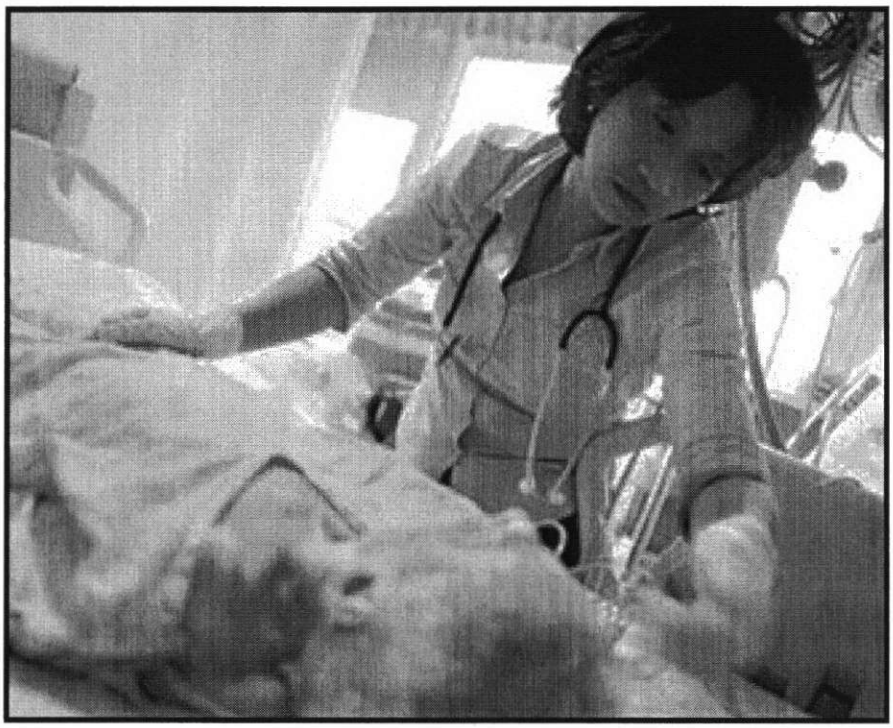
4 ■ Protocols should be challenged in formal ways as new technologies, drugs, and theories of practice are introduced in order to make them dynamic and constantly improving.

5 ■ Protocols should be viewed as students. They must be supervised and taught.

SOURCE: LDS Hospital, Salt Lake City, UT

LEVELS OF COMPLEXITY

Each protocol team is responsible for devising long-term outcomes monitors to measure effectiveness and retains permanent ownership for making future revisions. Less complex protocols, such as the monitoring and maintenance of potassium levels, are more straightforward than the multi-faceted protocol on sedation and paralysis of ventilator patients, which



has gone through frequent refinements, reflecting controversies and evolving philosophies of sedation management. "We used to sedate patients on vents until it was time for them to wake up. We don't do that any more. We found that getting them out of bed every day gets them off the vent faster," Clemmer says.

Other protocols address topics such as early enteral feeding of ICU patients to enhance bowel, biliary, and liver function and healing, along with indications, contra-indications, recommended formula, and tube placement; the monitoring of serum glucose levels for insulin drip patients; pain relief for conscious patients, and stress ulcer prophylaxis. The attending physician must order the protocol because it functions as a standing order – although some protocols are in use for nearly every patient.

More recently, the unit has started combining multiple protocols into clinical care pathways, such as a respiratory failure pathway. To date, this effort has not been as successful because of the complexities involved and the fact that some nurses don't always appreciate the numerous automated clinical reminders generated by the pathways, Clemmer says.

Some of the STRICU's protocols are kept in three-ring binders on the unit, with extra copies that the nurse can bring to the patient's bedside to provide clinical cues. Other processes, such as antibiotic selection and ventilator management, are computerized to provide more complex decision support. "We've become good at making the protocols very specific," Clemmer says.

Although some health professionals might object to such explicit protocols as "cookbook medicine," in fact, says nurse Susie Rimkus, using the protocols gives nurses more freedom and autonomy while challenging their critical thinking. Without the protocol, nurses would need to call the attending physician every time the patient's vital signs change. "They trust me as a nurse to have the knowledge and experience to apply the protocol. The nurse is expected to know why and to ask questions," says Rimkus, a ten-year veteran on the unit.

"Protocols are standardization of care – and an opportunity to discover methods to enhance the quality of care and achieve better outcomes. The nurse is highly trained in the protocol and applies it in a timely and aggressive manner. It's all spelled out so you give holistic care and you don't forget any single point," she says.

"Of course, we do not use the protocol blindly. You also need to be thinking about exceptions. And if someone has a better idea, we're open to hearing it." Following the protocols results in better outcomes, Rimkus adds, but when it's necessary to override the protocol, that, too, is an opportunity to learn and make improvements.

CULTURAL ISSUES ARE KEY

Just as important as the STRICU's clinical protocols are the cultural factors that have shaped protocol development on the unit and the ICU team's commitment to cooperation and communication, Clemmer says. Orme adds that the protocol process is an extension of the unit's commitment to integrated teamwork. "Each member of the ICU team has to feel and acknowledge the core value of every other member, both in terms of the position and the individual." Such respect has been inculcated by the unit's senior leaders and their example of collaborative problem-solving.

"If you have team members build and write the protocols together, there's a feeling of ownership," adds the STRICU's nurse manager, Lori Mitchell. Naturally strong nurse leaders who have the respect of their peers are tapped to head the protocol teams while charge nurses on the unit have been a constant in supporting their use.

Another key, Mitchell says, is to go back and make sure that protocols are being used and followed correctly – and that they're producing desired results. "My advice: if you think they're being followed, look again. We would do chart audits and find that they weren't being followed," she says. "Initially, they can be cumbersome, but once you know them, they make your job easier."

By continuing to work on its protocols, the STRICU advances quality of care, standardizes care processes, and minimizes medical mistakes, Clemmer concludes. "If we do it right the first time, we make patients better quicker." ■

Measuring Outcomes Beyond Mortality

RESEARCH TO ADVANCE THE ART OF QUALITY MONITORING IN A MEDICAL ICU

In order to satisfy itself that it was providing quality intensive care, one ICU has worked to develop new measures and new ways of understanding quality.

Intensive care units that are dedicated to the pursuit of quality often end up with the same kinds of programs designed to verify the results of their care and to continually improve care. The medical ICU (MICU) at 650-bed Lehigh Valley Hospital in Allentown, PA, established a quality improvement program with similar features as other leading ICUs. But it has tried to take its quality initiatives a step further, says medical director Dr. Stephen Matchett, looking at longer-term outcomes and families' satisfaction with ICU care in order to determine its real impact on the lives of critically ill patients and their loved ones.

The second profile in this report described the different paths to quality taken by three high-performing critical care departments in community hospitals – as well as the similarities in their programs – while the third described an established ICU that has longer experience in refining its data-driven quality improvement. Common features include installing intensivist-led multidisciplinary teams, designing sophisticated computer databases, using the data to continuously improve care, crafting menus of clinical protocols to define optimal care, and setting up monitoring systems to track compliance with those protocols.

"We have those things," Matchett says. "Our complication rates remain low and our length of stay is dropping," from 4.53 days in 1998 to 3.61 in 2001. The MICU received a research award from the Society for Critical Care Medicine in 1999 for demonstrating progressive reduction in severity-adjusted mortality. "But the issue for us is not just high-quality care and performance improvement. What makes this program unique is its attention to outcomes beyond 28-day mortality (a traditional ICU effectiveness measure), and developing the science to measure them."

The nine-bed MICU at Lehigh Valley, a university-affiliated community hospital, is part of a 32-bed critical care center that also includes trauma and surgical services. Matchett, a pulmonary intensivist by training, was part of a group of intensivists recruited by the hospital in 1995 to establish the MICU as an organized program. The unit has gradually evolved in the direction of a larger consultative role for its staff intensivists and in some cases mandated consultations. "Even though it's still an 'open' unit, we see 95 percent of the patients using a collaborative model, with care management decisions made by the multidisciplinary ICU team," he says.

"We started with the mission of building the clinical program and, along with it, a research program," which is now supported by an endowed chair in critical

Lehigh Valley Hospital
ALLENTOWN, PA

care medicine. Key to that mission, Matchett says, were a structured approach to quality and attention to carefully collecting clinical data. "You need medical and nursing leaders who look at the ICU as an entity – not a collection of patients. You need to manage that entity and you need tools for measuring and implementing the program." The MICU now has a rich clinical management database containing more than 4,000 consecutively admitted patients since May 1996 – and it uses the data to improve its quality.

From that jumping off point the MICU at Lehigh Valley ventured into new territory by continually asking the question: What is quality in critical care? Its conclusion: The traditional benchmarking standard for the ICU, adjusted 28-day mortality, is a somewhat blunt instrument that may miss the real determinants of quality, Matchett notes. "Our approach is that 28-day mortality is important, but it does not adequately define quality and may not be what's most important to many patients and families."

Death rates in ICUs are influenced by many factors, not just the severity of illness, reflected in current risk-adjusted mortality rates, or the quality of the care. For example, some patients might prefer to die rather than spend the rest of their lives severely functionally impaired and confined to a long-term-care facility. Some might forego ICU care for that reason, but in other cases the family may reach a conclusion to withdraw life-sustaining treatments on the patient's behalf only after a good-faith, but ultimately fruitless, effort by the ICU team to restore the patient's health. The patient may even die in the ICU – after all, only the most gravely ill patients are admitted – and yet the family could be extremely satisfied with the care that was given, according to Matchett.

New Approaches to Measuring Quality

The dogged pursuit of quality that defines all of the ICUs portrayed in this report led Lehigh Valley to create and validate a tool to measure families' perceptions of the quality of ICU care, to measure patients' actual functional status 90 days after they leave the hospital, and to emphasize *palliative care*, which provides comfort and support for the patient and family even in cases where recovery or survival is not expected.

When Matchett's quality team began exploring how to measure perceptions about the ICU experience, it realized that many ICU patients would be unable to rate their own care because they were so ill, sometimes unconscious, during their stay. That necessitated turning to the patient's loved ones for a surrogate evaluation of the care. The team also had to supplement previous research on measuring satisfaction with critical care. Pulling items from existing tools, it compiled a list of 72 questions and organized them into five domains: assurance, information, proximity, support, and comfort. Then it boiled them down to a workable set of 20 questions (see sidebar this page).

The tool was given initial reliability and validity testing, with results published in *Critical Care Medicine* (29: 192-196, 2001), then subjected to external validation at a Chicago hospital. One of the domains, comfort, needs further refinement, while how to use the tool is still a work in progress, Matchett says. But the MICU is already using it to gather data on how families view its care.

Issues that have started to emerge from the research include the quality of communication with the physician and other team members and the need to make discharge from the MICU less stressful. Other ICUs in the hospital, which has a combined total of 84 critical care beds, have also begun using the questionnaire. "For families who complete the survey and return it, there is high satisfaction overall," says Matchett. But the most valuable information for improving quality comes from families that are unsatisfied.

Future challenges for measuring family satisfaction include increasing the rate of return for the survey and figuring out how to directly tie the families' assessments with the care their loved ones received. Currently, completed family questionnaires are sent anonymously

Critical Care Family Satisfaction Survey

The 20-item survey used at Lehigh Valley Hospital asks for family members' responses, based on a one-to-five scale (very dissatisfied to very satisfied), to questions such as:

- Honesty of the staff about my family member's condition...
- Ability to share in the care of my family member...
- Clear explanation of tests, procedures, and treatments...
- Preparation for my family member's transfer from critical care...
- Peacefulness of the waiting room...

SOURCE: *Critical Care Medicine* 29(8): 1655, 2001

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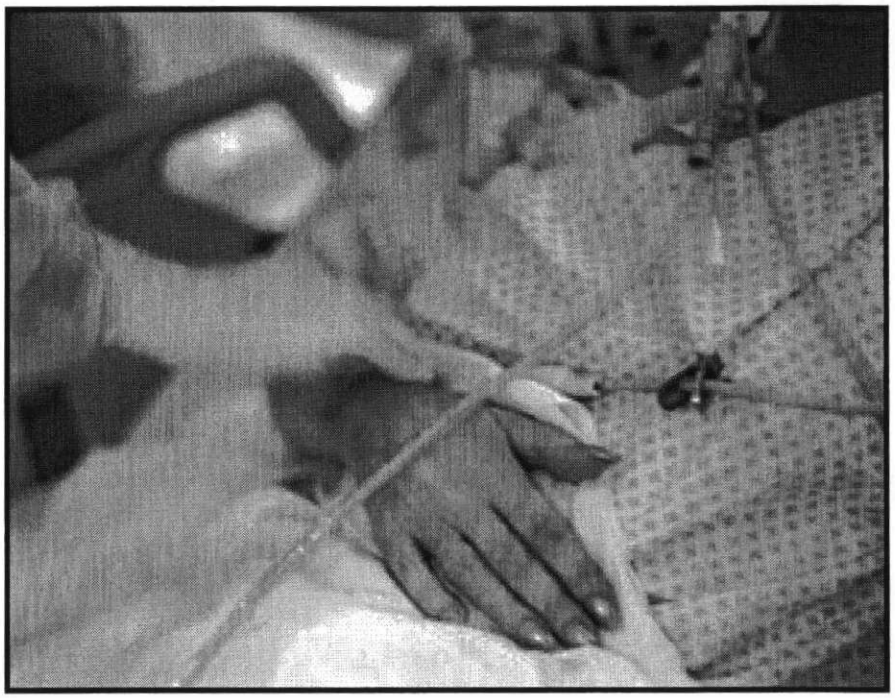

to the hospital's research department for tabulation, so it is not possible to identify common care elements related to dissatisfaction. But if researchers could devise a way to link the family survey with the patient's clinical chart, "it has the potential to answer a lot of important questions," says program coordinator Kathy Baker.

Another research initiative is looking at critically ill patients' functional status 90 days after they go home from the hospital, in order to start identifying risk factors for poor long-term outcomes. "What is the recovery of their functional status? Were they able to return to the life they were living before they got sick?" Matchett explains. The project is a collaboration with the hospital's Rehabilitation Department, using the Functional Independence Measure, a recognized evaluation tool in rehabilitation medicine, and professional assessments performed by trained physical therapists.

Although larger-scale research funding is being sought, the project has already begun to generate results. Patients are interviewed by the physical therapist while still in the hospital. Telephone surveys are conducted 30 and 60 days after discharge and the therapist conducts another assessment in the patient's home 90 days after discharge to actually see how well the patient is able to perform functional tasks of daily living.

A third target for more advanced quality measurement in the MICU, palliative or comfort care, may turn out to be the most difficult to measure, Matchett says. The focus of palliative care includes attention to physical symptoms such as pain and shortness of breath but also to the patient's and family's social, emotional, and even spiritual concerns – which makes its impact harder to quantify. "We see patients die, but was their care appropriate, compassionate, and high-quality?"

In 1997 the MICU adopted a palliative care protocol, developed in consultation with Lehigh Valley's hospice, palliative care, and pastoral care departments. MICU team members have since matured in their palliative care skills so that they can provide the needed supportive care themselves. "We do palliative care well, but it's all about trust," Baker says. "With shorter lengths of stay in the ICU, you need to develop that trust quickly."

Given that ICU deaths most often follow discussions and decisions to withdraw life-sustaining technology, the ICU physician is the best person to lead that conversation with families because of the intense bonds of trust that are developed, Matchett adds. "Once the decision is made to shift to a palliative approach, the ICU intensivist is also in the best position to carry it out," preserving continuity of care.

The Excitement of Quality Improvement

"When these doctors came in with their computer, the nursing department recognized the implications and went out on a limb by assigning me to data collection part-time," Baker says, recalling the MICU quality program's origins. "The doctors said, 'We are going to improve patients' care, we're going to do this with evidence, and we'll all do it together, as a team.'"

A former ICU bedside nurse, Baker has provided consistency to the quality initiative's data collection from its inception and now works full-time as program coordinator with responsibilities for research and for facilitating the MICU's Protocol Committee.

She worked closely with vendor Space Labs Medical of Redmond, WA, to improve the program's computer system. "It's an amazing phenomenon," she says. "It just feeds on itself and takes on a life of its own. The nurses are fascinated with the data. Other ICUs at our institution are getting on our bandwagon. They've seen how and why it works – it's very infectious," Baker says. "To see the whole process and to be able to contribute to quality improvement is what makes it all worthwhile."

Ultimately, Matchett adds, ICUs will need a more advanced scoring system for evaluating overall quality of care. Such a composite system might incorporate the patient's initial severity of illness, rates of complications during the ICU stay and other markers of the effectiveness of care, the patient's and family's perceptions of the experience, and the long-term recovery of physical function by the patient.

"We as a profession need to move beyond 28-day mortality rates. I think that's starting to happen, with the leadership of groups like the Society for Critical Care Medicine," he says. "I have tried to use scientific methods to measure what people say is important in critical care, although it hadn't been measured previously. If you can measure it, you can do something about it, and it's no longer just a vague concept." ■

Caring and Care IN THE ICU

THE RELATIONSHIP BETWEEN TECHNICAL INTENSIVE CARE AND THE HUMAN VALUES OF CARING

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Computer-based quality improvement points to opportunities for enhancing end-of-life care in a medical ICU.

Rhode Island Hospital
PROVIDENCE, RI

An exhibit of large framed photographs hanging on the walls of the medical intensive care unit (MICU) at Rhode Island Hospital in Providence, RI, mirrors the compassionate, high-touch care routinely given to critically and terminally ill patients on the technologically advanced unit.

Amid the tubes, wires, and monitors of contemporary intensive care, the staff strive to care for patients as though they were members of the family, says the unit's medical director, Dr. Mitchell Levy. At its best, the quality of caring in the MICU is about professionals behaving as decent human beings. And the photographs capture that quality in numerous intimate, caring moments between staff and the patients and their loved ones. Pointing to a picture of an ICU professional gently combing a critically ill patient's hair, Levy says, "Caring is in the details."

The MICU at Rhode Island Hospital has been celebrated for the quality of its caring and its emphasis on palliative care at the end of life as well as for its mastery of life-saving intensive care and commitment to refining clinical measures of the results from that care. But those different aspects of quality are not the separate realms that many health professionals have assumed, Levy asserts. In fact, the quality of the care and the quality of the caring are two sides of the unit's underlying commitment to excellence. Both are made possible by a sophisticated computer system that allows staff to measure and monitor subtle outcomes of care, he says, and quality is the common thread.

The Compassionate Care Photography Project, whose final product hangs on the MICU's walls, engaged local fine-arts photographers Bastienne Schmidt and Philippe Cheng to spend five days on the MICU at Rhode Island Hospital, freely

shooting all aspects of living and dying there. The photos have been exhibited at national critical care conferences, highlighted in educational videos produced by Ortho Biotech and the Society of Critical Care Medicine, and included in the pages of this report.

"We wanted to demystify the ICU. People forget that there's a lot more that goes on in the ICU than the technology," Levy says about the project. "To me these photos are all about compassionate care. What makes for good care and caring in the ICU is the human exchange between the professional caregiver and the patient."

The Sickest of the Sick

Rhode Island Hospital, with 719 beds, belongs to the Lifespan Health System and is the major teaching hospital for Brown Medical College, also in Providence. Levy was hired to direct the MICU in 1995; he spearheaded its move the following year into an expanded, 18-bed ward as well as its growing commitment to evidence-based medicine and protocol development.

The unit serves "the sickest of the sick," including patients with acute respiratory distress syndrome, chronic obstructive pulmonary disease, pneumonia, and multiple organ system failure. A significant proportion of the patients are on mechanical ventilators.

On a rotating basis, Levy and the unit's four other attending intensivists assume on-site medical management of patients on the closed unit. The nurses are part of a closely knit group that staffs from within. They have a high job retention rate and strong traditions both of supporting each other and of going beyond the call of duty to support patients and their loved ones. For example, they have been known to buy Christmas gifts for the needy children of a patient dying on the unit and even contribute to a patient's burial expenses.

"We have become a family and a community within ourselves, and we have learned to rely on each other," says assistant unit manager Susan Ross. Other members of the MICU team include the respiratory therapist, dietician, and pharmacist, as well as medical residents. "The heart of our collaborative model is that we're all patient advocates," Levy says.

The program's current evidence-based culture, which emphasizes monitoring and reporting adherence to written clinical protocols and includes a number of active research initiatives, began by "looking more closely at outcomes in critical care. Then we built a state-of-the-art computerized clinical information system," working with technology suppliers Hewlett-Packard and Philips Medical Systems to pilot new data management tools, Levy says. Computers in every room and at the nursing station offer team members instant access to patients' complete medical records.

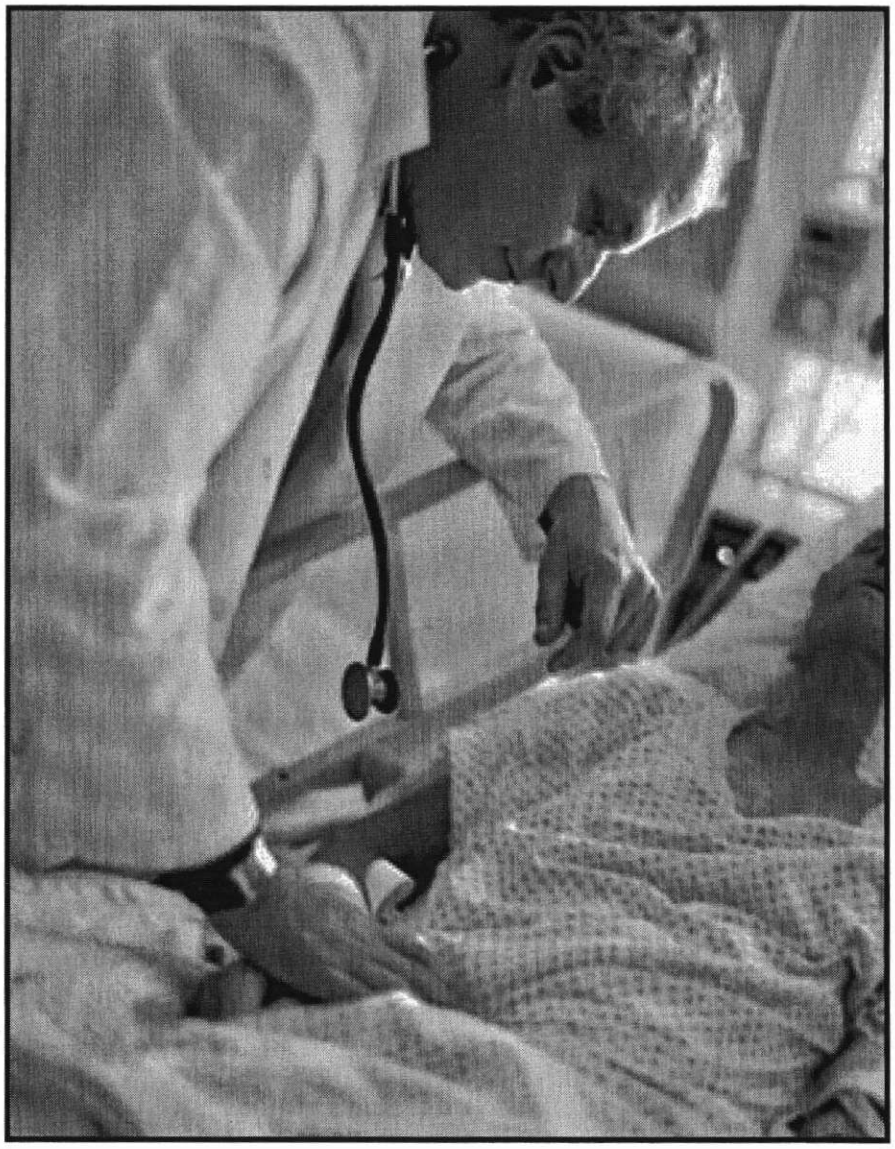
The data are entered on electronic flow sheets and automatically warehoused in the unit's relational database, from which management staff can query a wide variety of clinical questions on relationships between any data field and any other. This access to aggregated information on actual performance leads to reports, which are posted on the unit and shared with staff, to testing and implementation of new policies and procedures based on the data, and, ultimately, to improved quality of care.

"It's very easy to ask a question and get responses at set intervals," Ross says. "As a result, you can track better and start to see which treatments are being used, what results they produce, and which ones work best." When trends are identified, she says, the unit can change practice to continually improve patient care.

The introduction of electronic charting also led to better compliance with all levels of documentation, adds Donna Haze, nurse teacher on the unit. Instead of nurses handwriting notes for the chart as an afterthought to their other duties or hunting around for a paper medical record, everything is already lined up on the computer screen.

In some ways, the process of outcomes monitoring and compilation that goes on every day is invisible to nurses working on the unit because it is seamlessly integrated into their routine charting in the computerized medical record, Levy says. "Outcomes reporting is just good care at the bedside, using the computer to take what they do anyway and report it automatically" to an aggregated database.

Although the MICU tracks many of the same clinical outcomes as other ICUs, its clinical information system quickly



suggested different possibilities. "With these new tools we began to realize that traditional measures of quality, such as severity-adjusted mortality rates, were rather one-dimensional. We needed to dive down more deeply and look at more subtle aspects of quality," with the computer's support, Levy explains.

The Fine Points of Code Status

For the MICU's staff, the quality of caring on the unit for patients who may be at the end of their lives is inextricably linked to overall quality of care – and to opportunities created by the outcomes monitoring to base changes in care on the facts. "When we began to recognize that we could monitor subtle outcomes and aspects of quality, we realized that one of the subtle aspects of quality is end-of-life care," Levy says.

A key issue in such care is *code status*, which is a medical order reflecting the patient's preferences regarding invasive but potentially life-saving treatments, such as cardio-pulmonary resuscitation (CPR), under circumstances of advanced, life-threatening illness. Often, the patient in the ICU is physically unable to specify treatment preferences but may have previously expressed feelings on the subject, either conversationally or through a legal mechanism such as a living will or other advanced directive. If not, the ICU team is challenged to work with the family to get a sense of what the patient would have wanted under the circumstances.

Nurses meet with family members soon after an admission to the MICU, and the attending physician meets with them within 24 hours to clarify code preferences for the patient. Every day thereafter the issue is reconfirmed, and changes in code status are charted at four-hour intervals. Not all patients die in the ICU, but most often when there is a change in a gravely ill patient's code status, it is from "full code" – do everything medically possible to revive the patient – to "do not resuscitate" (DNR) if the patient's heart stops. DNR orders thus reflect a recognition that the ICU's life-sustaining treatments could not restore this dying patient to health.

The computerized clinical data system makes it possible to track the time span in which code status is changed. If such changes are made within 48 hours of admission, it might reflect a timely and meaningful dialogue between the ICU team and the family. Changes in code status that don't happen until weeks after admission, on the other hand, might indicate the absence of such dialogue but the prolonged provision of futile, intensive treatment. "Two thirds to three-quarters of code status changes on our unit happen within 48 hours of admission, which suggests that we are proactively matching the level of treatment offered with the patient's and family's wishes," Levy says.

Actual life-and-death decisions made on the ICU often are more complex and nuanced than the public image of "pulling the plug." Advances in medical science have greatly extended the ability to keep patients alive in the ICU, but can't always heal them or return them to former levels of functioning. Even in cases where the patient's previously expressed preferences are known, family members may not agree with each other or with the medical team's recommendations.

Sometimes the health care system has given anxious consumers too many medical choices that can overwhelm them

"When we began to recognize that we could monitor subtle outcomes and aspects of quality, we realized that one of the subtle aspects of quality is end-of-life care."

Thanks to television medical dramas such as *ER*, Americans are familiar with the more invasive aspects of chest pounding and paddle shocks used in CPR. Other times, just observing the ICU team at work speaks volumes to loved ones about the patient's condition. Some families may opt for not adding any new interventions but are reluctant to disconnect treatments already initiated.

"We try to keep the family updated, so it's never a surprise," says MICU nurse Beth Fucci about the process leading up to a decision to withdraw life-sustaining treatments. Families also need to believe that everything medically possible has been done to try to heal the patient. "It's a continuing process. It starts from the minute the patient arrives on the unit. We try to develop a caring, working relationship for having such conversations. We're always up front. We don't take away hope, but we're not going to give false hope."

Dr. Brian Kimble, an attending physician on the unit, and his colleagues are responsible for convening emotionally charged conferences with families and staff. Kimble tries to convey the medical picture to the family, complex though it may be, while also getting a clearer sense of their culture and values.

"The way I phrase it is: 'Did you ever have a discussion with your loved one about what they would want at a time like this?' That way, it's not about their own value judgment – it's about trying to put themselves in the shoes of the patient and telling me what that person would have wanted. It is important for families to not walk away feeling responsible for the decision. I try to ease them of any guilt and remind them that we're not killing the patient – we're just withdrawing artificial support," he says.

Such conversations require good interpersonal skills and respect for families and their perspectives. "It's as important as anything I do to manage the patient's care, and I think I'm pretty good at it," Kimble says. "The biggest wrinkle is that we don't really know what's going to happen to this person. Sometimes it gives me pause, and it makes me humble. I realize that I'm not God and I don't have all the answers."

What is End-of-Life Care in the ICU?

"When I think about end-of-life care in the ICU, it's about providing a level of care that is compassionate and responsive and that helps patients – whether or not they survive," Levy says. "Caregivers need to be brave enough to talk with families in a direct and honest way and build a relationship of trust. The first time I talk to the family should not be to say, 'I want to turn the machine off.'"

Although some patients die in the ICU despite the team's best efforts, their families will survive and remember for the rest of their lives the care given to their loved one, Levy says. "No one can take that pain away – only time can. But we can not make it worse, and not making it worse, in and of itself, can be healing."

The focus on quality end-of-life care in the MICU reflects important trends in ICUs – which are the setting for approximately one-fifth of all deaths. The national movement to improve care at the end of life originated outside of the ICU setting, primarily in specialized hospice and palliative care programs. However, in the past four or five years, ICUs have begun paying more attention to issues of death and dying, says Levy, who chairs a national ICU End-of-Life Peer Workgroup sponsored by The Robert Wood Johnson Foundation.

The priority placed on caring at the end of life in the MICU at Rhode Island Hospital can be seen in other policies such as 24-hour open visiting privileges and the availability of a quiet family room, which is often used for the conversations about treatment decisions. Families are encouraged by staff to observe medical treatments and sometimes to wipe the patient's brow or hands with a damp cloth. A family support team is available to meet with family members at the bedside to offer practical, emotional, and spiritual support for coping with the patient's illness.

Ross says the unit's focus on end-of-life care is "only at the tip of the iceberg. There's so much more we can tap into – even just figuring out what to measure, and opportunities to think about what we're doing – how to restructure our practice and protocolize end-of-life care. Talking about compassionate end-of-life care in the ICU is a recent trend in health care. Although we think we're doing a lot on this unit, I bet we can do so much more." ■

Restoring Profoundly Brain-Injured Patients

CLINICAL GUIDELINES LEAD TO DRAMATIC IMPROVEMENTS IN OUTCOMES

A multidisciplinary, multispecialty, evidence-based quality improvement initiative transforms the treatment of severe, traumatic brain injuries.

Mission Hospital Regional Medical Center
MISSION VIEJO, CA

In 1995, the Brain Trauma Foundation and the American Association of Neurologic Surgeons (AANS) issued a comprehensive set of national clinical guidelines spelling out optimal treatment for severe head injuries. The evidence-based guidelines, which scrupulously analyzed and ranked research in the medical literature based on its scientific validity, directly contradicted a number of long-established medical tenets. The majority of U.S. hospitals have yet to adopt the guidelines, which were revised in 2000.

But one unit that embraced the clinical and management challenges posed by the AANS guidelines is the surgical intensive care unit (SICU) at 331-bed Mission Hospital Regional Medical Center, a Level Two Community Trauma Center in Mission Viejo, CA. After carefully crafting and implementing its own "Clinical Guidelines for the Management of Severe Traumatic Brain Injury" (TBI), based on the AANS document and subsequent medical research, the SICU has posted extraordinary improvements in treating a condition that too often results in demoralizingly bad outcomes.

In the three-and-a-half years before Mission Hospital adopted its TBI guidelines in June 1997, 43 percent of severely brain-injured patients died, 30 percent ended up with severe disabilities or in a persistent vegetative state, and 27 percent experienced a good outcome or only moderate disabilities. While those numbers were not out of line with national averages for the treatment of TBI, the outcomes were not acceptable to the trauma team at Mission.

Within a year after its new guidelines were adopted, the proportion of the SICU's severe TBI patients achieving good outcomes or only moderate disabilities shot up to 64 percent. Cumulative figures for severely brain-injured patients in the four-and-a-half years since implementation show a mortality rate of 12.6 percent, with 11.6 percent having severe disabilities and 75.8 percent having good outcomes or moderate disabilities – and the proportion achieving good outcomes continues to rise. To state these accomplishments another way, since the guidelines were adopted at Mission, TBI patients have nearly nine times greater odds of a

good outcome from treatment than equally injured patients prior to the guidelines – with no significant differences between the groups in other variables that might explain away the results.

The 12-bed SICU, which is consistently full, also cares for patients with other traumatic injuries, as well as critical surgical patients. About 400 brain trauma patients are admitted to Mission Hospital each year and 30 to 40 of them are classified as severely injured. That typically mandates a prolonged, medically induced coma on a mechanical ventilator on the SICU to give the brain a chance to heal and the use of detailed, multidisciplinary treatment algorithms for every phase of the patient's hospital course.

The program begins even before a patient is admitted, with a radio call from an incoming paramedic to initiate the trauma protocol. A "trauma bell" rings overhead in the hospital, and a SICU nurse is assigned to meet the patient in the emergency room – which has special intake procedures for severe TBI admissions. The trauma nurse follows the patient to the operating room for emergency surgery and then to the ICU.

The SICU's TBI outcomes are attributed to the program's firm foundation on the best scientific evidence for treating severe brain injuries and the willingness of professionals at Mission Hospital to embrace new approaches to treatment – even when they diverge significantly from conventional methods. That openness, in turn, reflects the hospital's overall culture of professional collaboration, says neurosurgical clinical nurse specialist Mary Kay Bader, who spearheaded implementation and maintenance of the SICU's TBI quality improvement process.

Other trauma team members say that Bader's presence, advocacy, and coalition-building have been essential to the project's success. "Mary Kay brought something very unique to this hospital, and she has made a huge impact in how we treat TBI. She instilled the passion in me," says Mission Hospital's CEO, Peter Bastone.

"I see my role as a bridge – as point person. It's my job to get the whole process to flow," Bader relates. She functions in the role of clinical nurse specialist, a specially trained advanced practice nurse who deals with management and quality issues as well as clinical responsibilities. "Most days I spend the entire morning rounding, meeting with families, going to the ER, having occasional meetings, and doing education for SICU staff and for other nurses throughout the hospital."

How the Program Came About

Bader worked with physician champions to design the SICU's new approach to treating TBI, including leaders from the trauma surgery and neurosurgery groups that share medical management of TBI patients on the SICU. The original nucleus included neurosurgeon Dr. Sylvain Palmer, trauma surgeons Drs. Thomas Shaver and Marcello Borzatta, and trauma coordinator Connie Stalcup.

They assembled a 25-member quality improvement committee that included representatives from the neurosurgery and trauma surgery groups, anesthesiologists, pulmonary intensivists, nurses, and other professionals. They studied the literature and hammered out draft guidelines based on research data, quality models and templates, and chart reviews by Bader. The committee utilized a nine-step methodology commonly used in continuous quality improvement in devising the program and the guidelines.

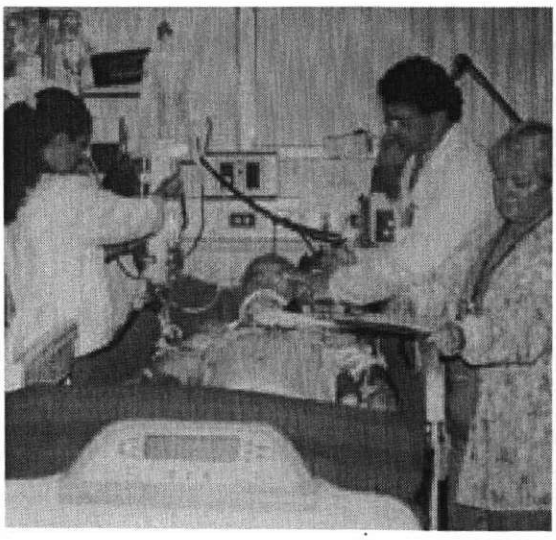
"You need champions from every piece of the partnership, and we had a quality process that we stuck to in terms of validating and re-validating our work," relates SICU director Mark Sevilla. "We based our work on the scientific research. Each constituent group was allowed to figure out how to do its own part of the program – but it had to be based on the evidence." When there were problems or variances, the group went back and critically reevaluated and revised the process, he says.

"In our training as surgeons and neurosurgeons, we were taught *ad nauseum* to dehydrate and hyperventilate the brain-injured patient in order to shrink the brain," thereby staving off secondary brain injuries caused by excessive swelling, Borzatta relates. That conventional approach, which had the goal of allowing the brain to heal by minimizing swelling and decompressing brain lesions, failed to account for its effect on cerebral oxygenation, the amount of oxygen the brain is receiving.

When the AANS panel examined the medical evidence, it reached very different conclusions at a time when new advances in monitoring brain tissue oxygenation levels made an alternate approach to brain resuscitation possible. Monitoring brain oxygen metabolism in the SICU today is done with the LICOX brain tissue oxygen monitor or a jugular bulb oxygen saturation catheter.

The essence of the new approach, Bader says, lies in "making sure we deliver enough blood and oxygen to the brain. Oxygen to me is the final pathway – the brain needs its oxygen to work." But there is a fine balancing act, making sure that intracranial pressure (ICP) doesn't get too great by closely tracking it through ICP

Surgical Trauma ICU at Mission Hospital. (From right to left) Mary Kay Bader, Neuroscience Clinical Nurse Specialist; Dr. Sylvain Palmer, Neurosurgeon; and Margie Whittaker, Nurse Manager SICU. *(Photo courtesy of Mission Hospital)*



needles stuck into the skull. For some patients, a craniectomy is needed – temporarily removing a piece of the skull to reduce the pressure.

"Our job is to keep the patient in the 'zone.' If one of the parameters gets too high or too low and the patient falls out of the zone, our guidelines contains standardized algorithms that we want the nurses to follow at the bedside to bring the patient back into the zone," Bader explains.

The Real Impact of the Guidelines

Today the SICU and its TBI program are recognized as a center of excellence within the hospital and its parent St. Joseph Health System and celebrated for their achievements. In 2000, the program received the prestigious Codman Award for exemplary quality improvement from the Joint Commission on Accreditation of Healthcare Organizations.

But to fully appreciate the impact of the TBI guidelines, trauma team members say, you would need to see how gravely injured the patients are during their critical first 24 hours in the SICU. Watching the extent of their recovery has motivated SICU team members – and the whole hospital – to extend themselves in making the process work better, Bader says. And their job satisfaction is reflected in a nursing turnover rate on the SICU of only 1.25 percent.

Nurse manager Brian Noakes says he was sold on the program the first time a severely brain-injured patient, whose recovery he had more or less written off based on past experience, started walking and talking and then returned to a normal life. Adds respiratory therapist Julie Petras, "It only takes one case like that – and we've had a lot of those cases. We had to learn to look at them in a whole different way."

Dr. James Cushing, medical director of the Acute Rehabilitation Unit at Mission, which often is the next stop for the most severely brain-injured patients when they "graduate" from the SICU, recalls a 16-year-old skateboarder who surprised everyone by recovering after smashing his head on the ground without wearing a helmet. "It was such a profound injury. When I saw him in the ICU, only minimally responsive, I'm afraid I was somewhat pessimistic about his prospects with the family, telling them, 'In my experience....'" Cushing relates. "Two months later, I was saying, 'Well, in my new experience, I've seen that people this badly injured can do very well.'"

The treatment approach contained in Mission's TBI guidelines actually costs more – at least in direct costs of intensive care, reflecting the need for specialized monitoring equipment, increased staffing levels, and one-to-one nurse-to-patient ratios in the early stages of TBI treatment. However, the comparison does not reflect eventual societal costs of long-term care and lost productivity that might be incurred for patients not managed according to the guidelines – not to mention the personal costs to patients and families. Sevilla says he has been challenged by hospital administrators to defend the greater expenditures and increased staffing, although not overruled on them.

CEO Bastone supported the TBI program from the beginning, but eventually even he had to question the rising expenses. "Finally, my chief financial officer said to me, 'Peter, this program is losing money.' So I got Dr. Palmer and Mary Kay Bader in my office and I asked them why these patients cost so much. Dr. Palmer said, 'Because they're living.' I almost fell out of my chair. Not only are they living, they're going home, going back to school or work, getting married," Bastone says.

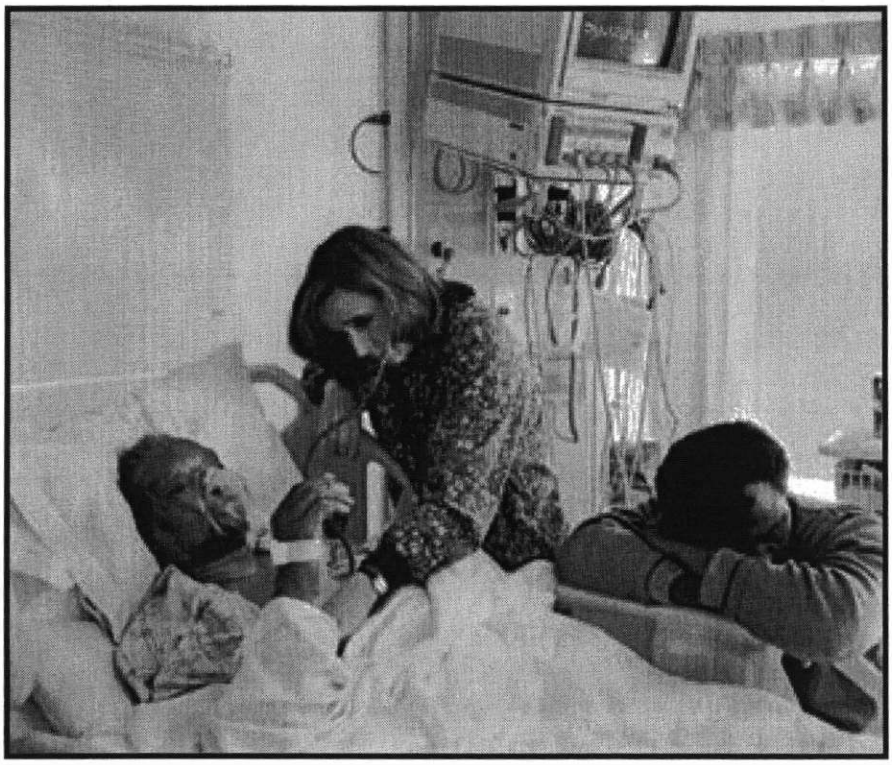
OUTCOMES FROM THE TBI Guidelines

Patients with severe traumatic brain injury before and after implementation of TBI clinical guidelines at Mission Hospital in June 1997:

		Pre-guidelines JAN 94 - JUN 97	Post-guidelines JUN 97 - DEC 01
Number meeting inclusion criteria		37	95
*Mean Glasgow Coma Score on Admission		6.4	6.8
*Mean 24-hour Glasgow Coma Score		5.2	5.4
OUTCOMES:	Good or moderate disability	12 (27%)	72 (75.8%)
	Severe disability	11 (30%)	11 (11.6%)
	Mortality	16 (43%)	12 (12.6%)
Mean charges with outliers		$196,128	$352,091

*NOTE: Glasgow Coma Score is a standardized numerical scale used in neurology to quantify a brain-injured patient's level of brain function from 3 (no response) to 15 (awake, aware, and follows commands).

SOURCE: Mission Hospital Regional Medical Center, Mission Viejo, CA



"The bottom line here is that we're saving lives." The mission-driven health system needs to consider more than just dollars and cents and to recognize the SICU's value as a center of excellence, he adds. And the "Wall of Fame" taped up in Bader's office, crowded with snapshots of smiling former SICU patients, underscores that point.

Another reflection of its success is the donation of more than $2.5 million from grateful families of patients treated on the SICU. The donations are used to support new equipment, family resources, and educational opportunities for staff. Twenty-year-old Adam Williams, who was gravely injured in a motorcycle accident in 1999, spent three weeks in a coma on the SICU; later, he enrolled in college. His mother, Nancy Williams, established the Adam Williams Brain Trauma Institute, a fund to support other hospitals to send staff to observe the TBI program at Mission and purchase new brain oxygen monitoring equipment, as well as enabling the Mission trauma team to go out and train staff at other hospitals.

With input from Williams and other family members, Mission Hospital decided to look at what happens to TBI patients when they graduate from the SICU and its protocols and high nurse/patient ratios. "We needed to do a better job of preparing families in advance for what to expect," Bader says, while the unit's approach of answering every question and encouraging families' participation wasn't always continued after the patient left the unit and moved to the acute surgical ward or rehabilitation unit.

In 2000 a group of professionals, former patients, and families was convened to explore the transition from the SICU. They broke into four groups to work on issues such as family support, continuity of care, and environment. One result is the "Family Education Notebook," which is given to every family of a severe TBI patient to define key medical terms and procedures and tell them what to expect from treatments.

Families of SICU patients often become experts in staging their loved ones on the Glasgow Coma Score (a numerical scale of brain function) and the Revised Rancho Scale of Cognitive Function from Rancho Los Amigos Medical Center. They also become informed and effective advocates when the patient moves to another unit. "We learned how much these families knew compared with before (the TBI guidelines), when they used to be entirely bewildered about their loved one's care," Cushing says. Rehab unit staff now meet patients and their families prior to SICU discharge.

Bader adds that SICU nurses have become hospital-wide ambassadors for a family-centered approach to care. Staff members that have completed training on the guidelines also wear TBI pins identifying them as reliable sources of information on the program.

True Collaboration, Not Just Lip Service

"This is truly a collaborative practice. We don't just pay lip service to teamwork. All members of the team are integrated," Palmer says. The TBI guidelines demand critical thinking, judgment calls, and understanding of the clinical priorities from nurses and other team members. "Our approach requires moment-to-moment responses, with decisions that have to be made on the spot – in real time," rather than tracking down the physician by telephone, he explains. "I can't be with the patient 24 hours a day. Collaboration means the nurses have to feel free to ask questions and believe that their input is important."

"I knew we had gotten to where we were trying to reach when one of the respiratory therapists was in another unit with a critical brain patient, and the nurses wanted to institute a treatment that the therapist thought was not in the best interest of the patient," Bader says. Based on his experience working with the TBI guideline on the SICU, he questioned the nurses on the procedure, but they said they wanted to do it anyway.

"He didn't get in an argument, but he came down to see me and told me what he'd seen – talking about physiologic parameters that you'd expect a nurse to know but not a respiratory therapist," Bader says. "I said, 'Why don't we go back up there together and talk to the nurses at the bedside?'

"It turns out he was right. What pleased me was that he really cared enough to take the initiative to come down and talk to me – and that he really understood what was going on with the patient." ■

Building a Kinder ICU

DEVELOPMENTAL AND ENVIRONMENTAL APPROACHES TO HEALING

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Two innovative ICUs, one for premature infants and the other for adult neurological patients, strive to make the noisy, invasive ICU setting a quieter, gentler place.

Memorial Medical Center
JOHNSTOWN, PA

Duke University Medical Center
DURHAM, NC

It is 5:30 on a Friday afternoon and a hushed calm prevails over the technologically advanced Regional Intensive Care Nursery (RICN) at Memorial Medical Center in Johnstown, PA. Overhead lights along the central corridor of the unit's premature wing are turned off, while softer lighting seeps out from a nursing station set back from the unit and from dimmed, recessed lights along the walls. Two neonatal nurses converse softly at the nursing station and a third approaches along the hallway, her steps echoing off the tile floor from afar. The only constant is the hum of an air conditioner fan; no crying is heard.

The RICN's critically ill patients – some of them born up to three months prematurely at a weight of not much more than a pound – are asleep in their incubators. Each baby's incubator is covered with a homemade quilt and watched over by a silent vital-sign monitor electronically connected to vibrating beepers carried by the nurses. Each incubator bay has a rocking chair and a recliner as well as a bank of several dozen electrical plugs and outlets. Occupied bays are decorated with photos and the artwork of older siblings. In one, hidden behind a full-length curtain, a new mother may be either nursing or "kangarooing" her tiny baby against her bare chest.

Flagship of the Conemaugh Health System in South Central Pennsylvania, 566-bed Memorial Medical Center was established by Clara Barton, founder of the American Red Cross, with memorial donations for victims of the 1889 Johnstown Flood. The RICN serves a 12-county referral base of critically ill "preemies" as well as full-term babies with serious cardiac or pulmonary diseases, infections, or other critical illnesses.

Census is down today in the RICN, which typically enters its busy season after Easter and admitted 179 babies in 2001. At one point last summer its 16 incubators were occupied by 18 infants, reflecting a policy of "co-bedding" tiny twins or triplets based on research suggesting that they have a special capacity for supporting each other post-term. But even when the unit is bursting at the seams, the nurses strive to carry out their work quietly and efficiently, reassuring anxious parents who may be watching.

PUTTING PATIENTS AND FAMILIES FIRST

Staff on the RICN emphasize a patient- and family-centered approach and an open visiting policy. That means cheerfully answering questions, allowing parents to observe medical procedures and participate in medical rounds, and encouraging them to become involved in their critically ill baby's care. The unit lets the parents be parents, in marked contrast to many ICUs where concerned family members are made to feel like "visitors" who are in the way of the medical care team.

"The instant they're comfortable changing diapers, they're changing diapers," or giving their baby a bath, notes the unit's nurse manager, Terry Trimeloni. "We try to establish from the beginning that it's *your* baby, and we're here to help. The more we can empower the parents, the better for everybody."

Other hallmarks of the RICN's approach include a comprehensive parent safety protocol, offering classes in home and car-seat safety and training in infant CPR (cardio-pulmonary resuscitation), and the nurses' efforts to "cluster" necessary medical procedures and vital-signs monitoring at the same time as feeding or changing, giving the babies more uninterrupted sleep. Occupational, physical, and speech therapy are introduced proactively, while the infant is still on the unit, based on research showing that earlier intervention produces better outcomes. Discharged families are also connected with home health care, scheduled for periodic follow-up clinic appointments, and even encouraged to call unit staff with questions long after their baby is sent home.

"When I started here in 1974, if we had a baby 28 to 29 weeks (gestational age) and weighing less than three pounds, often that baby died," Trimeloni says. "Today it's down to 23 or 24 weeks, and 29 weeks is a piece of cake. With the new technology we're able to save younger and younger babies. But our ultimate goal is for them not just to survive but to thrive."

THE DEVELOPMENTAL APPROACH

Policies such as the clustering of interventions, co-bedding of multiples, and the staff's encouragement for breast feeding and kangarooing (holding the baby on the parent's chest to make a skin-on-skin connection) reflect the unit's ruling philosophy of care, developmental supportive care. Developmental care strives to enable preemies to mature in a more "womblike" environment, based on their gestational age and appropriate level of stimulation for that age. It creates this environment by sheltering the infants as much as humanly possible from the bright lights, shrill alarms, invasive medical treatments, and sensory over-stimulation that typically define ICU care.

The developmental approach is credited to Dr. Stanley Graven of the University of South Florida, Tampa, and to a growing body of medical research suggesting that the assaults of light, noise, and painful procedures designed to save the lives of severely compromised, premature infants may have unintended consequences for their long-term health and development. The repercussions include damage to vision or hearing, learning disabilities, and behavioral problems, even difficulty bonding emotionally with parents who were not allowed to touch their premature baby during the first weeks or months after birth.

Developmental protocols for the unit include soothing infant massage, identification and charting of the infant's likes and dislikes, positioning for comfort, and using flashlights for procedures or – when that is not feasible – covering the infant's eyes as well as any nearby incubators.

Dr. John Chan, Medical Director of the Regional Intensive Care Nursery, examines a premature patient in a state-of-the-art isolette. *(Photo courtesy of Memorial Medical Center)*

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"We started out a long time ago just by noticing, 'Hey, it must be hard to lie in that bed all day and look up at those bright lights,'" says Trimeloni, who was one of the RICN's original staff nurses. "Over the past ten years, when we really started putting some of these ideas into practice, it became self-perpetuating. When you turned down the lights, you could just feel the unit going from chaos to a calmer environment."

The unit enjoys an extraordinary record of staff retention and longevity, reflected in its teamwork, collaborative spirit, openness to innovation, and passionate commitment to the babies entrusted to its care. Ten members of the unit's self-contained, 27-member staff have spent more than 25 years working on the unit.

Eventually, they discovered that what seemed to them just common sense was part of the emerging, evidence-based approach called developmental care. The unit's director, neonatologist Dr. John Chan, who started working at Memorial in 1995, attended a national conference on new developmental trends the following year. Then in 1997 he sent a multidisciplinary team of five unit staff,

"WITH THE NEW TECHNOLOGY WE'RE ABLE TO SAVE YOUNGER AND YOUNGER BABIES. BUT OUR ULTIMATE GOAL IS FOR THEM NOT JUST TO SURVIVE BUT TO THRIVE."

including nurses Mary Sava and Kim Shearman, to a conference on the subject. They returned eager to systematize and advance the ideas they had learned.

Veteran staff nurses had to learn to work in the dark and to stop talking or laughing loudly around the babies. "You had to see it to believe it," Shearman recalls. "Mary and I believed in it, but a lot of the staff were unconvinced and resisted at first. But once they saw the difference it made, their eyes opened up. Now they wouldn't have it any other way," she says. "The thing is, we weren't just making it all up. The (research) literature was out there. We read about it, experimented with it, and then just got fanatical about it."

THE MISSING PIECE: ENVIRONMENT

However, there was one serious drawback to this coalescing approach to care: the physical space the RICN had occupied on a temporary basis since it opened in 1974, attached to the hospital's maternity ward. With incubators crowded back to back, the space was too small for the kind of care the staff wanted to offer.

As the Conemaugh Health System began planning construction of a new hospital building, neonatal staff got involved in designing a new home for the unit. Drawing on the medical literature as well as their own experience, they offered suggestions and negotiated with the new building's architects. Although they didn't win every argument, they succeeded in creating a softer atmosphere in the new, environmentally enhanced setting, which opened in March 2001 with $300,000 in support from the hospital's foundation and Junior Auxiliary.

The staff's top priorities in designing the new unit were to include adequate space, 100 square feet for each incubator bay; to separate phones, washrooms, and storage areas from the incubators; and to designate rooms for a parents' lounge, a playroom for siblings, and two comfortable lodgings for parents to stay overnight in privacy. The popular lodging rooms are assigned to parents based on the distance they travel, their babies' medical acuity, and the need to create opportunities for them to practice caring for their babies in a more natural but supervised setting.

Sarah Runco utilized one of these family rooms, furnished more like a bed-and-breakfast than a hospital, for the three days that her baby, Celia, lived after being born with congenital anomalies incompatible with life. Runco found out at 20 weeks gestation that Celia was not likely to survive, but she planned with Memorial perinatologist Dr. Adib Khouzaimi and the RICN team to maximize the time she could spend with her baby, surrounded by her husband and large extended family.

When Celia was born, Runco relates, "I was thinking, 'Where are they going to put me? I don't think I could bear to be in a room next to a mother with a healthy baby.' To have that private room was the most important thing for us – to be a family by ourselves," she says. "I thought the nurses were the most wonderful people in the world. They helped take care of my family through it all. They taught me how to feed her with a feeding tube and syringe. They explained everything. I got to hold her skin to skin," she adds.

"Everyone on the unit knew Celia wasn't going to make it, but never once did they act like they were preparing for her death. They never made me feel I was wrong for loving this baby, knowing she was going to die." Staff even organized a birthday party for Runco's son Logan, who turned three while she was on the unit, complete with cake and presents. They also sent Runco home with a memory box of keepsakes, which she frequently opens as part of her process of grieving for Celia.

OUTCOMES TELL ONLY PART OF THE STORY

RICN staff members acknowledge the importance of incorporating the quality improvement techniques described throughout this report and of systematizing their practice. For example, grief support practices that had evolved on the unit for babies who died were formalized, with Chan's encouragement, into a grief protocol with a checklist that cues staff on the kinds of support to be offered.

Staffers also point with pride to the unit's performance on measurable outcomes, which compares favorably with national neonatal ICU averages in a hospital database compiled by the Vermont Oxford Network of Burlington, VT. For example, average length of stay on the unit for infants weighing less than 1,500 grams is 39 days, versus a comparable national average of 52 days. The eye condition known as retinopathy of prematurity, which occurs in almost half of comparably premature infants nationally, happens in less than one percent of the RICN's patients. And 78 percent of the young patients discharged from the RICN go home without diagnosed medical problems while the unit's death rate over the past decade is just two percent.

However, staff insist that there are aspects to their approach – the human side of their care, the spiritual underpinnings – that are not amenable to measurement. The quiet, soothing, family-friendly physical environment is important, but as a means to an end, which is healing the patient. In other words, Chan says, environmental enhancements, quality improvement, protocol development,

A new mother enjoys a private moment "kangarooing" her critically ill infant skin-to-skin, in a cubicle of the Regional Intensive Care Nursery. *(Photo courtesy of Memorial Medical Center)*

and other technical aspects of ICU practice are essential but not sufficient.

"We agree that we have to hone our skills so that we don't harm the patient. But now that we have not harmed the patient, have we truly healed that patient?" he explains. "Until we realize that what we are trying to improve is the care of a human being, we can be as technical as we want but it will always fall short." Without the team's deep commitment to the patients entrusted to it, the experience on the unit would not be as rich or successful, Chan adds. "But it works both ways. It's the lives we have touched and those lives that have touched ours – in a symbiotic rekindling of the spirit. Even if the patient dies, it wasn't a failure, it was somehow meaningful."

"When we turn out a baby to the world, we hope to give the parents a set of tools to be able to cope with the next steps in the child's life," Trimeloni says. The team strives to enhance parenting skills during extended stays on the unit, but also the parents' life skills, which might trickle down to other aspects of their families' lives.

A WARM FEELING IN THE HEART

Perhaps the best "evidence" for the RICN's success at caring can be found in frequent visits to the unit by former patients and their appreciative parents. At the unit's anniversary celebrations in 1994 and 1999, RICN staff greeted hordes of healthy "graduates" – from toddlers to high school and college students and even second-generation users.

A number of satisfied parents interviewed for this report, whose critically ill babies spent time on the RICN, acknowledge the importance of environment and the staff's technical competence. But they place higher value on the human face of the caring and the personal relationships they developed with professionals who cared for their babies. Mary Pullin, whose baby Lindsey was born at term but with serious breathing problems, says her experience staying overnight on the unit during the week Lindsey was hospitalized helped her to grow as a mother and become a better parent.

Sherry Frear, whose baby Jessica was born six weeks premature, recalls crying all the way when she was wheeled over in a wheelchair to see her gravely ill newborn in an RICN incubator. "From the moment I arrived, they made me feel like I was the most important person in that room, and all of my questions or concerns were important. Every baby, they treat it as if it were their own. They talk to it when they feed it. It's not like a job," Frear says. "When we left, I cried again. You just have such a warm feeling in your heart."

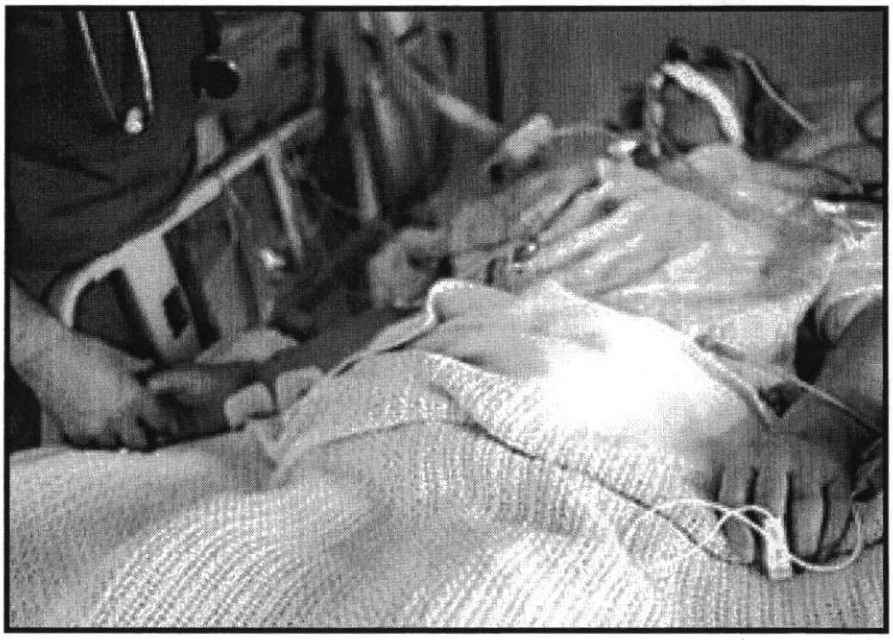
'QUIET TIME' IN AN ADULT ICU

Getting enough rest for healing can be just as important for adult ICU patients as for infants. But the unfamiliar environment, the noise and foot traffic, the frequent invasive medical interventions, the tubes for feeding and breathing, and the constant diagnostic work by nurses and other health professionals can make it hard for critically ill patients to get a good night's sleep. In fact, the noise levels in ICUs sometimes exceed noise pollution standards established by the Environmental Protection Agency.

All of those issues can be compounded for patients with serious neurological conditions such as traumatic brain injury, because of the intensive monitoring they receive. "We have a patient population in the neurological ICU that is getting constant stimulation – with a full neurological exam at least every hour," explains Robert Blessing, a nurse practitioner in the 14-bed neurological and neuro-surgical critical care unit at 1,124-bed **Duke University Medical Center** in Durham, NC, one of nine ICUs at Duke.

Neuro ICU nurses are challenged to try to see inside the patient's head, Blessing explains, in effect functioning like the vital-sign monitoring equipment used in other ICUs. "In our population, if the level of consciousness changes, even a little, it could have huge implications for managing the patient. We may need to immediately send them down for a brain C-T scan. The things you look for are any early signs of change."

Depending on the nature and severity of the injury, the neuro ICU nurse might perform ten minutes of neurological testing on the patient every hour – in addition to other interventions such as blood tests and ventilator or catheter maintenance. A full battery of such tests includes asking patients if they are awake, if they can open their eyes, move their pupils, and follow commands, and if they know where they are. Can they gag? If they can smile, is the smile symmetrical – or asymmetrical, perhaps a



symptom of a stroke? "You ask them to squeeze your hand, hold, push, and pull. It's a workout," Blessing says.

Needless to say, such an intensive exam every hour makes it hard for the patient to achieve a deep and restful sleep at any time. Heavy sedation of the type used on other ICUs usually is not an option for patients on the Duke unit, because it would interfere with the hourly assessment. However, a growing body of research is documenting the negative impact of sleep deprivation on the ICU patient – which veteran nurses have dubbed "ICU psychosis."

To address the dilemmas of sleep deprivation, nursing staff at the Duke neuro ICU devised a protocol called *quiet time*. Twice a day from 2 to 4 pm, and again from 2 to 4 am, most lights on the unit are turned down. Televisions are turned off; window shades are drawn. Visitors are asked to leave the unit, and attending physicians are encouraged to come back after 4. To the greatest extent possible, noise is limited, and the hourly exams described above are put on hold for two hours – unless the acute nature of the patient's condition makes that inappropriate.

Initial evidence suggests that quiet time gives patients a chance to catch up on deeper sleep, even just for two hours. According to research published in the *American Journal of Critical Care* (10: 74-49, 2001), implementing the protocol at Duke resulted in an increased proportion of patients observed asleep. The study also shows that it is possible to purposefully decrease light and sound in an adult ICU, although it remains a constant challenge to remind staff to respect the quiet time.

"The questions we haven't answered yet, which will take further study, include how it affects long-term outcomes," says Dr. Cecil Borel, an anesthesiologist, intensivist, and medical director of the neuro ICU. Further study targets include more intensive brain wave studies of patients, examination of whether quiet time makes a difference for sedated patients, study of whether some neuro patients need *more* stimulation rather than less, and exploration of new drugs that could promote normal sleep cycles in hospitalized patients.

The quiet time innovation and the research activities to validate its impact as a nursing intervention were both initiated by the unit's nursing staff, Borel notes. Encouragement of such initiatives reflects the collaborative, empowering nature of the unit and its interdisciplinary teamwork in which every team member has a say in clinical decision-making. The unit's faculty physicians encourage the nurses' interest in research and their personal stake in the unit's quality of care, providing statistical consultation and helping to obtain funding for special equipment when needed.

NURSES FUNCTIONING LIKE RESIDENTS

Another key nursing innovation on the unit is its program of acute care nurse practitioners (NPs) who provide 24-hour, on-site coverage and continuity of care. The seven-member neuro-intensive faculty, formed in 1994, could not provide the kind of on-site physician coverage needed to improve quality, expand the unit's size, and increase the complexity of care, Borel says. "So we needed to train nurses to be able to make medical decisions and to create a program that could provide the needed coverage."

Five nurses from the unit were recruited in 1996 to receive advanced education to become nurse practitioners. Since there were no existing training programs specific enough to the unit's requirements, a nurse practitioner program was created at Duke, under the leadership of Borel and former Duke nursing professor Joanne Hickey. The program was jointly founded and funded by Duke Hospital and the University's School of Nursing. Four NPs who remain from that initial training now take turns working 24-hour-plus shifts (with a few extra hours for rounding and orienting the incoming NP) and function much as medical residents do at other ICUs. They provide expertise, continuity of care, on-site decision making around the clock, and a foundation for quality of care.

Blessing, who worked on the Duke unit as a nurse for five years and considered attending medical school before learning about the NP training, says he loves his job. "I can use all of my nursing skills and also manage patients the way physicians do," with more autonomy. The NP role also includes performing complex medical procedures such as cardiac catheter insertion and lumbar puncture.

"Our nurse practitioners are like the ligaments holding this program together. They have the broad view" and serve as a communication link between attending physicians and ICU staff, adds DaiWai Olson, a nurse on the unit. "We have medical residents on the unit – but they're only here for a month. The NPs have been here for years. So now, when the residents come in, the NP is teaching them how to take care of the patient with brain injury." ■

Imagining the ICU of the Future

A HOSPITAL SYSTEM UTILIZES TELEMEDICINE TO ENHANCE INTENSIVE CARE

An exciting new integrated hardware, software, and telemonitoring program for remotely tracking the care of large numbers of ICU patients saves lives – and money.

Dr. Steven Fuhrman is a medical intensivist with a unique vantage point for monitoring critically ill patients. From his monitor-laden desk in an office suite in an industrial park in Norfolk, VA, Fuhrman is looking into the future of the intensive care unit.

Using telemedicine over secure T1 lines and state-of-the-art computerized decision-support technology and software provided by VISICU, a critical care technology firm in Baltimore, MD, Fuhrman is able to closely track evolving vital signs and other clinical early-warning indicators for 50 critically ill patients at one time. The patients are in five ICUs in three different hospitals of the Norfolk-based Sentara Healthcare system, at distances of 7 to 25 miles. A remote-controlled camera, microphone, and speaker mounted in each patient's room allow Fuhrman to see the patients – even though he can't physically touch them – and converse with them and staff.

While it is the science fiction aspect of Sentara's "electronic ICU" (eICU) that has captured the attention of the medical and general press, even more dramatic are the program's results. (See box on page 34.) In its first year of operation in the first two ICUs to go on-line, the program reduced the length of ICU stays and of those patients' overall hospital stays while achieving a 24 percent reduction in ICU mortality rates – representing 60 lives saved per year relative to severity-adjusted projections. In addition, the program generated net cost savings of at least $3 million for Sentara on a $2 million investment in eICU operating costs. The savings resulted from reduced resource utilization, fewer complications, shorter average stays, and revenue-enhancing opportunities to refill freed-up beds with new patients.

The program's creators emphasize that the eICU is an overlay on existing ICU staffing and structures and is not intended to replace the attending physician's responsibility for managing his or her critically ill patients. But it offers enormous potential for maximizing scarce resources, including intensivists, critical care nurses, and ICU beds. They add that the telemedicine-based program has measurably improved job satisfaction while helping

Sentara Healthcare
NORFOLK, VA

to prevent burnout among critical care professionals. Eventually, it could be used to leverage critical care resources into smaller hospitals that could not afford or attract intensivists for their own ICUs.

Life at the "COR"

How has this revolutionary new program, the first of its kind to fully implement VISICU's technology, achieved such dramatic results? The answer requires a closer look at the eICU itself, dubbed the "COR" or Clinical Operating Room by its denizens, housed in a nondescript office building shared with lawyers, shipping companies, and state offices.

For Fuhrman, who is also the eICU's medical director, his Friday shift began at noon, and he will be spelled by another intensivist at 7 pm. (The eICU equipment lies idle from 7 am to noon, prime hours for attending physicians to visit their patients and conduct on-site medical rounds in the ICUs.) Other members of the eICU team this afternoon include critical care nurse Leslie Martin and two clerical support staff. They share the room with about 15 computer monitors in various configurations, as well as a conference table, fax machines, and telephones, including "hot lines" directly linked to the five units' nursing stations.

Fuhrman's desk is crowded with four linked monitors. A screen lists all 50 wired ICU patients, classified as red, yellow, or green based on the urgency of their medical needs. Another monitor accesses the video connection to each patient's room or displays real-time vital sign data for one unit or shows the summary page from a single patient's electronic medical chart, collecting pertinent data such as medications, therapies, and a task list of current care priorities. Another screen summarizes VISICU's *smart alerts*, which silently analyze heart and respiration trends for all of the patients, using computerized rules engines and thresholds defined for each patient by the eICU physician. Those patients who have trended toward or crossed the thresholds get marked for closer attention.

Once an hour Fuhrman and Martin "scroll" through charts, tracking recent vital sign and laboratory data for each of the 50 patients, looking for emerging small problems that could be addressed before they become large, life-threatening problems. Using a computer mouse, Fuhrman rapidly clicks from screen to screen, field to field, chart to chart, with the ease of a video game wizard, sometimes stopping for a closer look and reflectively stroking his goatee. "The patient is brought to me by a simple point and click," he says. "I will tell you the system is very easy to learn. I was trained in several hours after seeing the software for the first time."

When any of the multiple data sources suggests that an unhealthy trend might be emerging, Fuhrman can pick up the phone and call the attending physician or the nurse's station or else put on a headset and activate the video camera in the patient's room. Whenever he calls up the video camera, he presses a "doorbell" on his desk that rings in the patient's room, announcing that he and the camera are now on line. He zooms the camera in on the patient's face, pans to the left where a family member sits bedside, then to the right where a nurse has just entered the room. By adjusting contrast and close-up, he can identify the contents of intravenous fluid drips and notes written in grease pencil on a bulletin board of additional data hanging on the back wall.

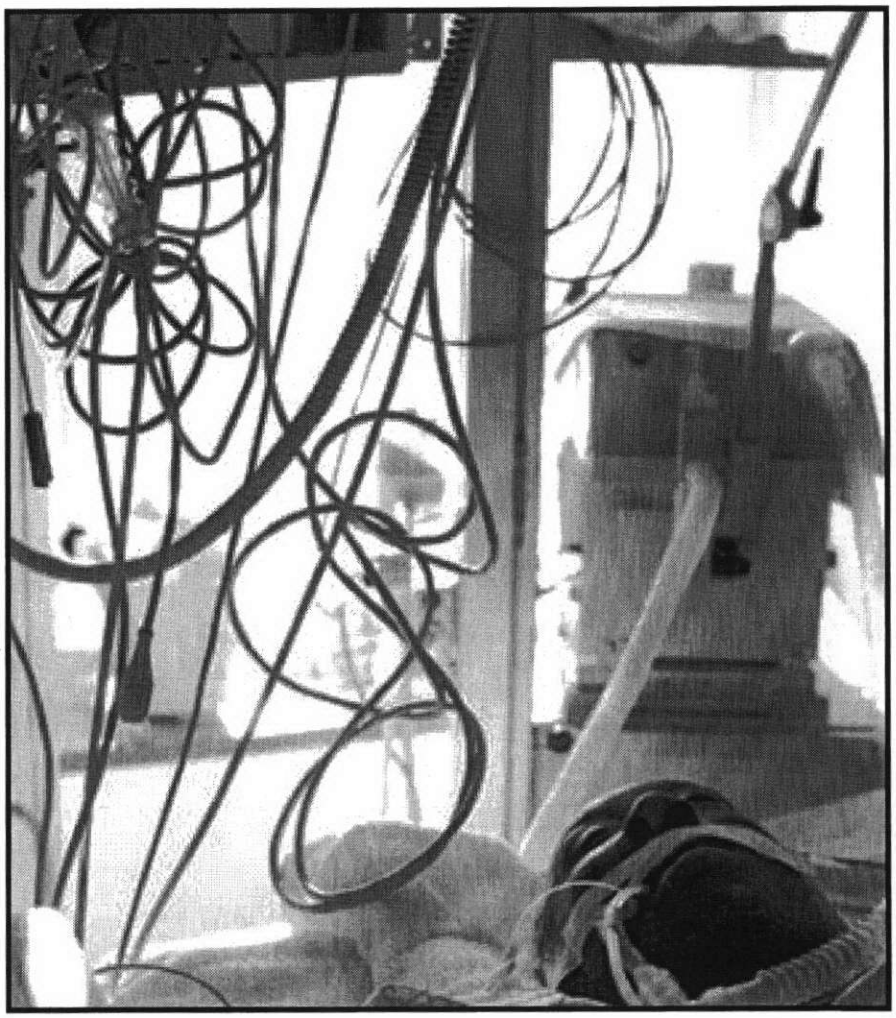
A Desk Chair Response

As in the majority of American hospitals, the ICUs in the Sentara system do not have 24-hour, in-person presence of medical intensivists, although the system's critical care specialists are available on-call for consultation when requested and involved in managing the ICUs. The patient's attending physician retains primary responsibility for medical manage-

OUTCOMES FROM Sentara's eICU

The electronic ICU was implemented in June 2000 in two ICUs in Sentara Norfolk General Hospital. Results from the first nine months of 2001 were compared with baseline data from the 12 months prior to implementation, annualized, and analyzed using the APACHE III severity index (a commonly used measurement technique). Independent financial analysis was conducted by Cap Gemini Ernst Young. Among the findings:

- Average length of stay for critical care patients went down 17% (from 5.19 to 4.36 days in the general ICU and from 2.92 to 2.43 days in the vascular ICU)
- Bed turnover in the ICUs increased 20%
- During the first nine months of 2001, there was a 23.9% reduction in overall ICU mortality and a 15.1% reduction in hospital mortality for ICU patients
- Cost per patient went down $2,150
- Based on a program investment of $1.9 million, the eICU generated annualized savings of $4.9 million (in the most conservative analysis), resulting in net savings of $3 million – or a 155% return on investment



ment of his or her patient in the ICU, in collaboration with specialists, and visits the patient daily.

Sentara's ICUs are just as busy and noisy as other ICUs and are staffed, managed, and supervised in much the same way as they were before the eICU system went on line in June 2000. The familiar vital signs monitors hanging over every bed are programmed to sound an alarm whenever defined clinical thresholds are crossed, drawing a prompt response from the patient's primary nurse. Normally, when the patient's condition indicates the need for a change in medical orders, the nurse would page the patient's physician. When the physician calls back, the nurse describes the problem; the doctor asks questions and then must decide whether to order medical changes over the phone or come to the unit in person.

At Sentara, the eICU physician's monitoring and the smart alerts provide additional layers of quality and safety while reducing after-hours demands on the primary physician and the other intensivists. From his desk-chair perspective in the eICU, Fuhrman can spot trends, focus on areas of concern, and thoughtfully consider whether a response or watchful waiting is indicated. If a patient isn't responding to treatment as expected or starts to show early signs of an impending cardiac or pulmonary arrest, the smart alert offers a gentle tap on the eICU doctor's shoulder. The doctor can proactively start a ventilator, order additional tests, read test results that have just come back from the hospital lab, and get started on addressing the problem – rather than waiting until the attending physician shows up for rounds the next morning.

All of these systems aim to prevent or minimize medical complications – which are the bane of ICU patients' lives and a significant driver of mortality, length of stay, and resource expenditure for the hospital – eliminating errors of omission and achieving a more streamlined, standardized response. It's not a matter of brilliant, aha, deductions, Fuhrman says, it's just staying a step ahead. "Our data show that additional morbidities and complications are avoided. By handling developing problems early, before they get full blown, you reduce the need for the intensivist as fireman."

Cutting-Edge Technology

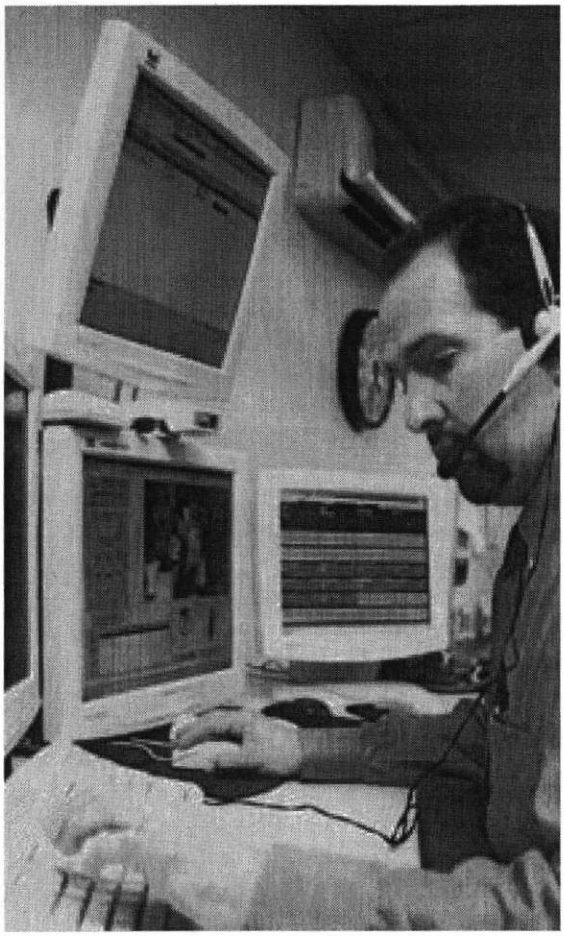
VISICU, the technology firm that created this model of remote ICU monitoring, was founded by two medical intensivists formerly at Johns Hopkins Medical Center in Baltimore, MD, Drs. Brian Rosenfeld and Mike Breslow. "We saw two important issues: quality of care in the ICU and a national scarcity of intensivists," at a time when advances in technology were making a whole new approach to those issues imaginable, relates Rosenfeld, the company's executive vice president.

A 1997 experimental trial of remote ICU management showed the feasibility of ICU telemonitoring and led them to form their company. A personal connection between Sentara CEO David Bernd and a retired colleague who was advising VISICU led the health system to volunteer as beta test site for VISICU's integrated hardware and software product, with the two organizations collaborating closely and learning together on its shakedown cruise.

Its software package includes an electronic medical record; *The Source*, a computerized, evidence-based clinical decision support tool; and "smart reports," which are automatically generated from the multitudes of data on clinical performance for each patient that stream through the system every day. Without having to manually reenter such data, Sentara can track overall quality and generate reports on clinical performance in its ICUs.

In the beginning, VISICU managed and helped to staff the eICU in Norfolk, working with a medical group of pulmonary intensivists at Sentara, although responsibility for the unit's management reverted entirely to Sentara in July 2002.

The medical group provides much of the medical coverage, working with local



Dr. Steven Fuhrman monitors 50 patients in ICUs of Sentara Healthcare from his post in the electronic ICU. *(Photo by Susan Martin Leichtman/courtesy of Sentara Healthcare)*

naval doctors, faculty from a nearby medical school, and community physicians. A total of 18 intensivists rotate through the eICU, but they all have other medical responsibilities and find the occasional shift in the COR a stimulating contrast.

Where to Go Next

Sentara's system of six community hospitals serves a population base of two million in Southeastern Virginia's Tidewater region. Its flagship facility, 664-bed Sentara Norfolk General Hospital, a tertiary care center affiliated with Eastern Virginia Medical College, housed the first two ICUs to go on-line, a vascular and a general ICU. Currently, Sentara's six hospitals contain 16 adult ICUs with 160 beds.

Only 50 beds are wired to the eICU, but the program has generated tremendous interest throughout the system in the possibilities of telemedicine and in critical care generally, says Dr. Gary Yates, Sentara's Executive Medical Director in charge of clinical effectiveness. "As a result of the data we have produced, there is much more support among physicians for the intensivist model."

Sentara had previously recognized the challenges of critical care and launched a performance improvement project spanning all of its adult ICUs, Yates adds. The Critical Care Leadership Council was appointed to work on performance improvement, protocol development, and best practices for the ICUs. Sentara also participated in a national ICU collaborative project sponsored by the Institute for Healthcare Improvement.

However, the pace of implementing changes such as protocols and standards of care was also shaped by the political realities of its community hospitals and 700 physicians who have ICU admitting privileges. Making Sentara's ICUs closed – having unit intensivists take over medical management of patients admitted to the ICU – would have been difficult, notes Dr. Gene Burke, head of the Sentara intensivist medical group that leads the eICU project. In a different political arena than academic medical centers, the eICU offered a new way to address quality and the need for intensivist supervision in the ICU.

To implement the project, the health system instituted four levels of involvement that attending physicians could specify for their patients. (No eICU involvement at all is not an option on the wired units.) At Level I, the eICU functions largely as an alarm system, responding only to emergencies. At Level IV, the eICU doctor essentially takes the existing care plan and manages it from 12 pm to 7 am, although the primary physician remains involved and informed. Initially, most physicians opted for Level I but, based on the project's impressive results, the majority now chooses Level III or IV.

The system is still exploring questions of how many more beds can be wired to a single eICU – at an equipment investment of about $30,000 to $50,000 each – and what configurations of doctors and nurses could most efficiently monitor larger numbers of patients. Another question is which units or other hospital partners should be wired up next, with expansion proceeding as quickly as implementation issues can be worked out.

"It opens all sorts of possibilities," says Mark Gavens, administrator of Sentara's Southside Hospitals Division. An eICU based at a tertiary medical center could be used to build closer relationships with referring rural hospitals and leverage the expertise of the center's medical intensivists. "You think: 'What a way to build partnerships with overlapping communities!'" Gavens says.

Another benefit of the eICU project at Sentara is its potential for preserving the careers of experienced ICU physician specialists. The intensivists, with their on-call responsibilities and nighttime interruptions after a hard day job in the ICU, were in danger of having to leave the field prematurely.

"Our group of intensivists are all in their mid-40s to early 50s," Burke relates. The group embraced the eICU concept as a better way to manage ICU patients but also to save the doctors' careers from potential burnout, he says. Working the night shift in the COR is hard work mentally, but not as taxing physically. And when the scheduled night shift ends, the doctor gets to go home and go to bed, with the next day off. ICU nurses, too, have the opportunity to rotate through the eICU and incorporate the new technology into their careers.

Burke and his colleagues acknowledge that the eICU hasn't exactly made their lives sedate, given the challenges of implementation, filling the shifts, and finding new doctors to help staff the program – although they have been invigorated by the opportunity to participate in creating a dramatically new model of care. "But I see this as a stepping stone, offering more ability to change my work environment and make it into something that would be sustainable," says Burke. ■

Resources and Suggested Reading

Several organizations mentioned in this report maintain websites that offer considerable information on health care quality. Among them are:

- www.nchc.org
- www.ihi.org
- www.ahrq.gov
- www.leapfroggroup.org
- www.jcaho.org
- www.nqf.org
- www.vha.org

SELECTED ORGANIZATIONS

Society of Critical Care Medicine
701 Lee Street, Suite 200
Des Plaines, IL 60016
PHONE 847-827-6869
WEBSITE www.sccm.org

Dedicated to ensuring excellence and consistency in the practice of critical care medicine, the Society of Critical Care Medicine offers a variety of activities that promote quality in patient care, education, research and advocacy.

International Trauma Anesthesia and Critical Care Society
P.O. Box 4826
Baltimore, MD 21211
PHONE 410-235-8084
WEBSITE www.trauma.org/ITACCS/about.html

ITACCS is a non-profit professional society dedicated to developing the education and practice of trauma specialists around the world.

American Society of Critical Care Anesthesiologists
520 N. Northwest Highway
Park Ridge, Illinois 60068-2573
PHONE 847-825-5586
WEBSITE www.ascca.org

The Society serves the specialized needs of intensivists as well as the broader needs of practicing anesthesiologists. A video on the practice of perioperative medicine and anesthesiology is available on the site.

Institute for Critical Care Medicine
1695 Sunrise Way, Bldg. 3
Palm Springs, CA 92262
PHONE 760-323-6867
WEBSITE www.911research.org

A comprehensive international center for research, study, and information in the medical, technical, ethical, and health economics field as they pertain to immediate life-saving medical care.

American Association of Critical-Care Nurses
101 Columbia
Aliso Viejo, CA 92656-4109
PHONE 800-899-2226
WEBSITE www.aacn.org

AACN is committed to providing high quality resources to maximize nurses' contribution to caring and improving health care for critically ill patients and their families. The organization offers educational materials, updates on clinical practices, and certification materials.

Critical Care Forum
WEBSITE http://ccforum.com/start.asp

CCforum features recent research on critical care, clinical guidelines, and educational reviews of clinical practice.

ICU-USA.com, Inc.
12444 Powerscourt Drive, Suite 300
St. Louis, MO 63131-3620
PHONE 314-453-0853
WEBSITE www.icu-usa.com

The site is designed to clearly explain to patients ICU-related medical conditions, drugs, procedures, equipment, and supplies.

The Leapfrog Group
1801 K Street, NW, Suite 701-L
Washington, DC 20006
PHONE 202-292-6713
WEBSITE www.leapfroggroup.org

Comprised of more than one hundred public and private organizations that provide health care benefits, the Group works with medical experts throughout the U.S. to identify problems in the health care system.

PedsCCM: The Pediatric Critical Care Website
WEBSITE www.pedsccm.org

A collaborative information resource and communication tool for professionals caring for critically ill children.

Medscape by WebMD
WEBSITE www.medscape.com/criticalcarehome

Medscape's section on critical care contains conference coverage, news, upcoming events, and a comprehensive library.

Wright's Anesthesia and Critical Care Resources
WEBSITE www.eur.nl/fgg/anest/wright/contents.html

Database of links and Internet resource materials relevant to critical care.

Project Impact
WEBSITE www.projectimpacticu.cc

An organization dedicated to providing ICU practitioners, hospitals, health care systems, critical care researchers, and insurers with the data, information, and related products and services that enable them to continually measure and improve patient safety and outcomes while minimizing resource utilization and cost of care.

ARTICLES AND BOOKS

Pronovost, P.; Wu, A.W.; Dorman, T.; Morlock, L. "Building safety into ICU care." *J Crit Care*, 2002, Jun; 17(2):78-85.

This manuscript provides a framework for improving safety in ICUs and includes a detailed case discussion.

Burns, J.P.; Mitchell, C.; Griffith, J.L.; and Truog, R.D. "End-of-life care in the pediatric intensive care unit: attitudes and practices of pediatric critical care physicians and nurses." *Critical Care Medicine*, 2001, 29:658-664.

This study examined the attitudes and practices of pediatric clinicians on end-of-life care.

Pronovost, P.J.; Kenckes, M.W.; Dorman, T.; Garrett, E.; Breslow, M.J.; Rosenfeld, B.A.; Lipsett, P.A.; and Bass, E. "Organizational characteristics of Intensive Care Units related to outcomes of abdominal aortic surgery." *JAMA*, 1999, 281:1310-1317.

Organizational characteristics of intensive care units are related to differences in outcomes of abdominal aortic surgery among hospitals. Not having daily rounds by an intensive care unit physician is associated with an increased risk of cardiac arrest, acute renal failure, septicemia, platelet transfusion, and reintubation as well as a significant increase in in-hospital mortality.

Multz, A.S.; Chalfin, D.B.; Samson, I.M.; Dantzker, D.R.; Fein, A.M.; Steinberg, H.N.; Niederman, M.S.; and Schraf, S.M. "A 'closed' medical intensive care unit (MICU) improves resource utilization when compared with an 'open' MICU." *Am J Respir Crit Car Med*, 1998, 157:1468-1473.

This article compared 'closed' intensive units with 'open' ones, and determined that 'closed' intensive care units are more efficient and that mortality is not adversely affected.

Dimick, J.B.; Pronovost, P.J.; Heitmiller, R.F.; and Lipsett, P.A. "Intensive care unit physician staffing is associated with decreased length of stay, hospital cost, and complications after esophageal resection." *Crit Care Med*, 2001, 29:753-758.

Shorter lengths of stay, lower hospital costs and less frequent complication after esophageal resection are associated with having daily rounds by an intensive care unit physician.

Pronovost, P.J.; Dang, D.; Dorman, T.; Lipsett, P.A.; Garrett, E.A.; Jenckes, M.; Bass, E.B. "Intensive care unit nurse staffing and the risk for complications after abdominal aortic surgery." *Eff Clin Pract*, 2001, 4(5):100-205.

This large study describes the association betweein ICU nurse staffing and reduced morbidity and lengh of stay in patients having major surgery. When patients are cared for by fewer nurses, they have increased risk of pulmonary complications and increased length of stay.

Bergeron, N.; Skrobik, Y.; and Dubois, M.J. "Delirium in Critically Ill Patients." *Crit Care Med*, 2002, 6:181-182.

Traditional psychiatric evaluations cannot be used to diagnose critically ill patients with delirium for a variety of reasons. This article strongly recommends user friendly reliable tools such as the Confusion Assessment Method for the Intensive Care Unit.

"Evidence-based medicine: a new approach to teaching the practice of medicine." Evidence-Based Medicine Working Group, *JAMA*, 1992, 268:2420-2425.

Evidence-based medicine shies away from intuition and emphasizes examining clinical evidence.

Jonhe, B.D.; Appere-De-Vechi, C.; Fournier, M.; Tran, B.; Merrer, J.; Melchior, J.C.; and Outin, H. "A prospective survey of nutritional practices in intensive care unit patients: what is prescribed? What is delivered?" *Crit Care Med*, 2001, 29:8-12.

Physicians need to be more stringent about providing appropriate nutritional support for the critically ill.

Dominuez, T.E; Chalom, R.; Costarino Jr., A.T. "The impact of adverse patients occurrences on hospital costs in the pediatric intensive care unit." *Crit Care Med*, 2001, 29:169-174.

This retrospective cohort study found that complications in intensive care units are associated with increased lengths of stay. Infectious complications are better predictors of costs than vascular or airway complications.

Wu, A.W.; Pronovost, P.; Morlock, L. "ICU incident reporting systems." *J Crit Care*, 2002, Jun;17(2):86-94.

This manuscript reviews incident reporting systems and discuss the ICU safety reporting system (ICUSRS). Dr Pronovost is the principal investigator on this AHRQ funded project that is implementing web-based incident reporting in over 30 ICUs.

Sibbald, W.; Bion, J.F. *Evaluating Critical Care: Using Health Services Research to Improve Quality.* (New York, NY: Springer Verlag) 2001.

The book describes how the integrated approach offered by health services research can improve the quality of care provided to critically ill patients.

Curtis, J.R., & Rubenfeld, G.D., eds, *Managing Death in the Intensive Care Unit: The Transition from Cure to Comfort* (New York: Oxford University Press) 2001.

The editors focus on the clinical and practical aspects of providing end-of-life care for patients, as well as ethical, legal and societal issues.

Marino, P.L. *The ICU Book.* (Philadelphia, PA: Lippincott Williams & Wilkins) 1998.

The ICU Book is a disease-oriented generic text for adult intensive care units.

JOURNALS

Journal of Critical Care, published by WB Saunders Company, edited by William Sibbald

This quarterly presents basic and clinical research, pertinent reviews, ethical and legal controversies, and important abstracts in the area of critical care.

Current Opinion in Critical Care, published by Lippincott Williams and Wilkins, edited by Jean-Louis Vincent

The journal features literature reviews, bulleted and annotated references, and a comprehensive bibliography, in six issues per year.

American Journal of Respiratory and Critical Care Medicine, edited by Martin Tobin, published by the Thoracic Society

The articles in the American Journal, an official journal of the American Thoracic Society, consist predominantly of original scientific research.

Critical Care Medicine published by Lipincott, Williams and Wilkins

The official journal of the Society of Critical Care Medicine is a source for multidisciplinary coverage of all aspects of acute and emergency care.

PREPARED BY ELIANA SUSSMAN,
NATIONAL COALITION ON HEALTH CARE

FOR ADDITIONAL INFORMATION ON THE QUALITY IMPROVEMENT PROJECTS PROFILED IN THIS REPORT PLEASE CONTACT:

Making a Science of Patient Safety
A Systematic, Eight-Step Quality Process in Surgical ICUs

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Decreasing Costs by Improving Care
Data-Driven Quality Improvement Programs in Three ICUs

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Refining the Art of Protocols
Experience, Commitment to Collaboration Lead to More Sophisticated Protocols

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LDS Hospital
8th Avenue and C Street
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EMAIL tclemme@ihc.com

Measuring Outcomes Beyond Mortality
Research to Advance the Art of Quality Monitoring in a Medical ICU

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Allentown, PA 18105
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Caring and Care in the ICU
The Relationship Between Technical Intensive Care and the Human Values of Caring

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Restoring Profoundly Brain-Injured Patients
Clinical Guidelines Lead to Dramatic Improvements in Outcomes

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Building a Kinder ICU
Developmental and Environmental Approaches to Healing

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Imagining the ICU of the Future
A Hospital System Utilizes Telemedicine to Enhance Intensive Care

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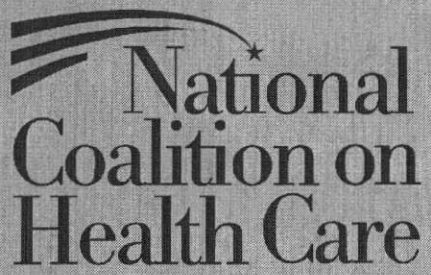

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3.6

Critical care delivery in the intensive care unit: Defining clinical roles and the best practice model

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Patients receiving medical care in intensive care units (ICUs) account for nearly 30% of acute care hospital costs, yet these patients occupy only 10% of inpatient beds (1, 2). In 1984, the Office of Technology Assessment concluded that 80% of hospitals in the United States had ICUs, >20% of hospital budgets were expended on the care of intensive care patients, and approximately 1% of the gross national product was expended for intensive care services (3). With the aging of the U.S. population, greater demand for critical care services will occur. At the same time, market forces are evolving that may constrain both hospitals' and practitioners' abilities to provide this increasing need for critical care services. In addition, managed care organizations are requesting justification for services provided in the ICU and for demonstration of both efficiency and efficacy. Hospital administrators are continually seeking methods to provide effective and efficient care to their ICU patients. As a result of these social and economic pressures, there is a need to provide more data about the type and quality of clinical care provided in the ICU.

In response, two task forces were convened by the Society of Critical Care Medicine leadership. One task force (models task force) was asked to review available information on critical care delivery in the ICU and to ascertain, if possible, a "best" practice model. The other task force was asked to define the role and practice of an intensivist. The task force memberships were diverse, representing all the disciplines that actively participate in the delivery of health care to patients in the ICU. The models task force membership consisted of 31 healthcare professionals and practitioners, including statisticians and representatives from industry, pharmacy, nursing, respiratory care, and physicians from the specialties of surgery, internal medicine, pediatrics, and anesthesia. These healthcare professionals represented the practice of critical care medicine in multiple settings, including nonteaching community hospitals, community hospitals with teaching programs, academic institutions, military hospitals, critical care medicine private practice, full-time academic practice, and consultative critical care practice.

This article is the consensus report of the two task forces. The objectives of this report include the following: (1) to describe the types and settings of critical care practice (2); to describe the clinical roles of members of the ICU healthcare team (3); to examine available outcome data pertaining to the types of critical care practice (4); to attempt to define a "best" practice model; and (5) to propose additional research that should be undertaken to answer important questions regarding the practice of critical care medicine.

The data and recommendations contained within this report are sometimes based on consensus expert opinion; however, where possible, recommendations are promulgated based on levels of evidence as outlined by Sacket in 1989 (4) and further modified by Taylor in 1997 (5) (see Appendix 1).

DEMOGRAPHICS AND PATTERNS OF CARE IN ICUS IN THE UNITED STATES

Several databases have described the demographics and patterns of care in ICUs in the United States. This section

The American College of Critical Care Medicine (ACCM), which honors individuals for their achievements and contributions to multidisciplinary critical care medicine, is the consultative body of the Society of Critical Care Medicine (SCCM) that possesses recognized expertise in the practice of critical care. The College has developed administrative guidelines and clinical practice parameters for the critical care practitioner. New guidelines and practice parameters are continually developed, and current ones are systematically reviewed and revised.

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*See Appendix 6 for a complete listing of members.

‡See Appendix 7 for a complete listing of members.

Key Words: critical care nurse; intensive care unit; intensivist; organizational characteristics; outcome; outcomes assessment; pharmacist; practice patterns; respiratory therapist

describes the methods used to establish these databases and their major findings, focusing primarily on critical care practice patterns.

Society of Critical Care Medicine Study (1991)

In 1992 and 1993, the Society of Critical Care Medicine (SCCM) reported the results of a 1991 survey of all ICUs in the United States (6, 7). The American Hospital Association provided the database used for the survey. The survey response rate was 40%, with 1,706 hospitals providing data on 2,876 separate ICUs with 32,850 ICU beds and 25,871 patient admissions. The survey demonstrated that nationally, 8% of all licensed hospital beds were designated as intensive care. Adult and pediatric ICUs averaged 10–12 beds per unit, whereas neonatology units averaged 21 beds. Overall, ICU occupancy averaged 84% of total ICU beds. Small hospitals with <100 beds usually had only one ICU, whereas larger hospitals, particularly those exceeding 300 beds, tended to have multiple ICUs, most commonly designated as medical, surgical, and coronary care.

Management and organizational structure varied widely. Departments of medicine had responsibility for 36% of the ICUs, whereas 22% had no formal departmental affiliation. Internists directed 63% of all ICUs. Most surgical and neurologic units were directed by surgeons, as were 21% of the mixed medical/surgical units. Full-time unit directors were present in 20% to 60% of the different hospitals surveyed. The smaller hospitals (<100 beds; 20% had full time directors) were less likely to employ a full-time unit director compared with larger hospitals (>500 beds; 60% had full time directors). Further findings indicated that 61% of directors were part-time, 51% were unpaid, and 56% were not certified in critical care medicine. Smaller hospitals (20%) had a lower percentage of board-certified unit directors compared with larger hospitals (56%). The ICU medical director, or designee, authorized admissions to the ICU in 12% of all the ICUs surveyed. Pediatric (31%), neonatal (30%), and surgical units (20%) were most likely to have medical directors who authorized unit admissions. As hospital size increased, the likelihood that the unit director had final authority regarding admissions also increased. In hospitals with <100 beds, the unit director had such authority in 9% of the hospitals, whereas in hospitals with >500 beds, this authority was present in 56%. Responsibility for patient care was transferred to the ICU service in 15% of all units surveyed. The ICU service had exclusive medical order-writing authority in 22% of the units (closed unit). Open units were those in which any physician could write orders. Resident physicians dedicated to the ICU were present in 6% of the smallest hospitals compared with 95% in the largest hospitals. The percent of nurses that were certified as critical care RNs increased as hospital size increased: 16% ≤100 beds; 21% >500 beds. Forty-eight percent of units reported having dedicated respiratory therapists, with a median of two therapists per unit.

Pediatric ICU Survey Data (1989)

In 1993, the results of telephone surveys conducted in 1989 of all pediatric ICUs in the United States were published (8). Of 301 hospitals initially believed to have pediatric ICUs (PICUs), data were collected from 235 (78%). Most PICUs had four to six beds (40%). Only 6% had >18 beds. The ICU mortality rate differed significantly among ICU size groups, with the largest units having the highest mortality (7.8 ± 0.8%). Full-time ICU medical directors were present in 80% of the hospitals. In 64% of the units, the medical director or designee was involved in the care of >90% of the patients. A consistent charge nurse was available in 90.6% of the units.

Committee on Manpower for the Pulmonary and Critical Care Societies (COMPACCS; 1997)

To document current and future needs for critical care and pulmonary specialists, the American Thoracic Society, the American College of Chest Physicians, and the SCCM organized COMPACCS in 1995. As part of this study, random samples of hospitals and hospital-appointed ICU directors were surveyed. Pediatric ICUs and units designated as cardiac care were excluded from the COMPACCS survey.

In the survey, ICU directors described the characteristics of their units and patients on the day the survey was completed. To characterize the role of intensivists in ICU care, the ICU directors used the following definitions to describe the care provided to their patients.

a) Full-time intensivist model, wherein all or most of a patient's care is directed by an intensivist (where an intensivist was defined as an attending physician who, by training or experience, provides care for the critically ill in a role broader than that provided by a consultant specialist).
b) Consultant intensivist model, wherein an intensivist consults for another physician to coordinate or assist in critical care but does not have primary responsibility for care.
c) Multiple consultant model, wherein multiple specialists are involved in the patient's care (a pulmonologist or intensivist might be consulted for ventilator management, but no one is designated specifically as the consultant intensivist).
d) Single physician model, wherein the primary physician provides all ICU care without involvement of an intensivist or other consultant.

General ICU Statistics. At the time of the survey, there were 5,979 noncoronary ICUs in the United States, consisting of 72,500 beds with an average occupancy of 77% (average number of beds per unit was 12, with an average census of 9.2). The large majority of ICU beds and patients were in general medical or general surgical units, with an approximate national ICU census, in the spring of 1997, of about 53,000 patients (personal communication; 9).

Patterns of Care. Nearly all of the patients described in the survey could be classified into one of the four patterns of medical care described previously. Of the 53,000 patients, 23.1% were treated in an ICU utilizing the full-time intensivist model, 13.7% utilizing the consultant intensivist model, 45.6% using the multiple consultant specialist model, 14.2% using the single physician model, and 3.4% using some other model. The demographics of the care patterns are described in Table 1 (personal communication; 9).

Regression analysis of these data indicate that the use of the full-time intensivist was statistically associated with larger hospitals, higher managed care penetration, and medical ICUs (MICUs). There was no consistent relationship between patient population size and the full-time intensivist model.

ICU Organization and Staffing. Of all ICUs surveyed, the administrative re-

Table 1. Demographics of care patterns

	Full-Time Intensivist	Consultant Intensivist	Consultant Specialist	Single Physician
Hospital size				
Small	12[a]	07	50	30
Medium	09	14	55	20
Large	40	14	37	04
Very large	36	19	34	10
Type of ICU				
General (33,112)[b]	19	13	46	17
MICU (16,752)	47	17	33	03
SICU (7,510)	21	18	45	14
Specialty (5,455)	21	13	52	14

ICU, intensive care unit; MICU, medical ICU; SICU, surgical ICU.

[a]Values reflect percent of total care provided by each model in each row; total may not add up to 100% because "other" category was not included in the table; [b]numbers in parentheses represent the total patients nationally in that category.

sponsibility was assigned to clinical departments as follows: anesthesia, 0.6%; medicine, 36.7%; surgery, 16%; free standing, 29.1%; and other, 17.6%. Intensivists provided clinical care in 60% of surveyed ICUs, with an average of 12.7 staff members identified by the ICU director as intensivists. Training and/or board certification in critical care were common for these intensivists, ranging from an average of 50% for general internists to 88% for pulmonologists.

In-hospital physician coverage varied. Hospital staff physicians, in roles that varied from attending physician to admitting physician to emergency back-up physician, were formally assigned to cover 30% of the ICUs. During daytime hours on weekdays, this role was fulfilled, on average, by 3.6 staff physicians geographically assigned as follows: full-time presence in the ICU, 27%; presence elsewhere in the hospital, 44%; or presence off-site, 24%. On nights and weekends, 70% of the full-time coverage was directed from off-site and, on average, by two staff physicians. Residents were assigned to cover 44% of all ICUs. Residents were assigned full-time ICU coverage in 53% of hospitals surveyed, in-hospital presence with ICU cross-coverage in 42%, and other in 5%. Fellows were assigned to cover 21% of the ICUs surveyed, with 47% full-time in the ICU, 40% cross-coverage in the hospital, and the remainder off site. Less than 10% of surveyed ICUs reported using nurse practitioners or physician assistants. This coverage almost always required their presence in the hospital, and approximately half of this coverage was full-time in the ICU.

From these data, generated from surveys conducted about 10 yrs apart and primarily in adult critical care units, there are some consistent patterns. About one third of the ICUs are administered by the department of medicine, one-fourth have no departmental affiliation, and 60% of all ICU patients are in general ICU units. The full-time intensivist treated 23% of all ICU patients. This role was particularly common in large hospitals and especially in MICUs. House staff and fellow coverage were employed in 44% and 21% of all ICUs, respectively. In contrast, ICU coverage by nonphysicians was very uncommon.

CRITICAL CARE PRACTICE MODELS

Multidisciplinary Critical Care

The information derived from the aforementioned surveys can be used to describe various models of critical care practice. In a joint position statement, published in 1994, SCCM and the American Association of Critical Care Nurses advocated for a multidisciplinary approach to the administrative and clinical practice of intensive care medicine (1, 10, 11). The governing bodies of the organizations espoused collaboration and shared responsibility for ICU team leadership as a fundamental part of optimizing the medical care provided to critically ill patients. Carlson et al. (12) further outlined five characteristics of the multidisciplinary, collaborative approach to ICU care:

1. Medical and nursing directors with authority and co-responsibility for ICU management.
2. Nursing, respiratory therapy, and pharmacy collaboration with medical staff in a team approach.
3. Use of standards, protocols, and guidelines to assure consistent approach to medical, nursing, and technical issues.
4. Dedication to coordination and communication for all aspects of ICU management.
5. Emphasis on practitioner certification, research, education, ethical issues, and patient advocacy.

This multidisciplinary approach to the management of critically ill patients may be an important factor in the quality of care provided in the ICU. The presence of a team of health professionals from various disciplines, working in concert, may improve efficiency, outcome, and the cost of care for patients hospitalized in the ICU (12–31). An essential element of the ability of a multidisciplinary team to effectively attain specified objectives is team dynamics. Only recently has the impact of team dynamics been applied to medical care delivery teams, and it is important to note that team dynamics may differ given the time allowed to accomplish the objective (i.e., emergently, urgently, routine). As a result, in the ICU, it is essential that the physician team leader and the critical care nurse manager collaborate in the education, structure, and evaluation of the team's dynamics (32, 33).

A detailed description of this multidisciplinary approach to critical care practice has been further outlined by recent American College of Critical Care Medicine (ACCM) and American Academy of Pediatrics recommendations for services and personnel required to provide critical care medicine to adults and children hospitalized in ICUs (34, 35). These recommendations represent the consensus report of experts in critical care medicine.

Certain aspects of the document pertaining to adult ICUs require clarification to highlight the recommendations and support for the multidisciplinary approach to critical care medicine (34).

1. Comprehensive critical care units should be directed by an intensivist, as defined by the SCCM, in collaboration with a defined nursing director (36).
2. Patient management should be directed by an attending physician who is credentialed by the hospital medical staff to provide care to critically ill patients.

3. Critical care attending physicians should be available to provide bedside care within 30 mins, and in-hospital ICU physician coverage must have sufficient expertise to provide emergency management including, but not limited to, airway emergencies.
4. All nursing care should be provided by critical care trained nurses.
5. Respiratory therapists with a working knowledge of the principles of respiratory failure management should be dedicated to the ICU 24 hrs per day.
6. Pharmacy services should be available to provide ICU-dedicated pharmaceutical care and consultation.

In the pediatric document, published jointly in 1993 by the American Academy of Pediatrics and SCCM, the multidisciplinary approach to critical care medicine is described for the pediatric ICU. Characteristics of the medical and nursing directors, types and availability of physician staffing, and availability of a dedicated team of healthcare practitioners specifically trained in the area of pediatric medicine are described (35). A state government, in formulating statewide quality standards for PICUs regarding equipment, space, and personnel (37), has recognized the multidisciplinary approach to pediatric critical care medicine, outlined in this article.

Physician Component—The Intensivist

In 1992, the SCCM guidelines committee described the functions of and requirements to be an intensivist (36). Specific qualifications and responsibilities for an intensivist are outlined in Appendix 2. The most important role of the physician intensivist on the critical care team is as the coordinator and leader of the multidisciplinary, and often multispecialty, approach to the care of the critically ill patient. The critically ill patient is defined as any patient who is at risk for decompensation or any patient who is physiologically unstable, requiring constant surveillance and minute-to-minute titration of therapy according to the evolution of the disease process. The geographic location of the patient in the hospital does not limit the need for critical care, but rather, it is the nature of the illness that defines the care needed. The treatment of the critically ill patient begins immediately on recognition of the severity of illness, continues as the patient is transferred into the ICU, and extends into the recovery phase until the potential for decompensation is sufficiently low.

An intensivist is responsible for coordinating and providing integrated care to the patient with acute and chronic complex illnesses. To accomplish this, proximity to the patient is required. During scheduled intervals, the intensivist practitioner must be immediately available to the patient in the ICU and have no higher priority that would interfere with the prompt delivery of patient care. At times, other specialty consultation is necessary. When multiple consultants are involved, the intensivist, acting as the multispecialty team leader, coordinates the care provided by the consultants, thus providing an integrated approach to the patient and family.

The intensivist participates in and coordinates ICU management activities necessary for the safe, efficient, timely, and consistent delivery of care. Key to these ICU management responsibilities is vesting the authority and providing resources and administrative medical staff leadership. These responsibilities include the following: 1) patient triage based on admission and discharge criteria, bed allocation, and discharge planning; 2) development and enforcement of, in collaboration with other ICU team disciplines, clinical and administrative protocols that are intended to improve the safe and efficient delivery of clinical care and to meet regulatory requirements; 3) coordination and assistance in the implementation of quality improvement activities within the ICU.

The intensivist takes a lead role in meeting the emotional and informational needs of the family during a patient's admission to the ICU. He/she facilitates and collaborates with other team members to provide support for the family in conjunction with that of nursing, ministerial services, and social service team members. The intensivist has the skills to counsel families and to address ethical issues of care by providing the family with the knowledge and support that is needed to make informed decisions regarding the patient's care. This includes, but is not limited to, end-of-life decisions.

The physician component of critical care practice can assume several patterns. Categorizing critical care practice patterns is difficult because there are many variations depending on institutional bias, geographic distribution of physician manpower, and regional availability of financial resources. These critical care practice patterns begin by describing the physician intensivist role in the coordination of care for critically ill patients and often further describe the interrelationships between the physician intensivist and ICU administrative structure.

Much of the medical literature categorizes ICUs as "open" or "closed." These terms have been defined in several ways. In the analysis published by Groeger et al. (6), open refers to units wherein any physician could write medical orders and closed refers to units wherein only the ICU physician staff could write medical orders. Others have defined the terms in a broader context and added a third type of unit called "transitional" (12, 38). As described by Carlson et al. (12), and further adapted here, the characteristics, advantages, and disadvantages for the units are outlined below.

Open Units. Any attending physician with hospital admitting privileges can be the physician of record and direct ICU care; the presence or absence of a dedicated intensivist physician and nursing unit directors; the presence of ICU-dedicated house officers variable; the potential for duplication of services, the lack of a cohesive plan, and inconsistent night coverage.

Closed Units. An intensivist is the physician of record for all ICU patients; full-time ICU directors (physician and nursing); house officers usually present and usually full-time dedicated to the ICU; all orders and procedures carried out by ICU staff; potential for improved efficiency and standardized protocols for care; potential to lock-out private physicians and increase physician conflict.

Transitional Units. An intensivist director, trainees, and intensivist team are present as locally available; standard policies and procedures usually present; shared co-managed care between ICU staff and private physician; encourages optimal communication between ICU staff and community physician; may reduce physician conflict; ICU staff is the final common pathway for orders and procedures; potential for confusion and conflict regarding who has final authority and responsibility for patient care decisions.

ACCM has also described practice pattern models and definitions as follows (personal communication).

Attending Physician of Record. An ICU is an "open unit" when any attending

physician with appropriate hospital admitting privileges can be the patient's physician of record and has ultimate responsibility for the quality and coordination of care. All other physicians are consultants. An ICU is "closed" when the intensivist automatically becomes the attending physician of record for all patients admitted to the ICU. All other physicians are consultants.

Physician Commitment. There can be a spectrum of commitment to the ICU. One example includes the full-time intensivist group of physicians, geographically dedicated to the 24-hr coverage of the ICU, wherein a qualified physician is immediately available to the ICU and has no clinical commitments other than the ICU. In contrast are physicians who provide intermittent coverage by making rounds and responding to emergencies but who also have simultaneous clinical responsibilities other than the ICU.

It is the assertion of this task force that the aforementioned ACCM definitions and those described by Carlson et al. (12) encompass nearly all patterns of medical practice in the ICU setting that pertain to the physician-patient practice pattern. In examining outcome data, these unit classifications and physician practice patterns are often cited, and as such, the definitions are important.

Nursing Component

Although an in depth description of critical care nursing practice is beyond the scope of this document, specific standards of care and practice are outlined in Appendix 3. The section below describes nursing practice in the ICU, focusing on the relationship between nursing and physician practice in the ICU.

Critical care nursing traditionally includes, but is not limited to, the roles of staff nurse, nurse manager, clinical nurse specialist, and acute care nurse practitioner. Critical care nursing practice focuses on several areas.

1. Understanding and supporting technical medical care, including diagnosis, treatment, care planning, and priority setting. In this role, the nurse partners with the ICU attending physician to provide care and oversight to the plan of care ensuring that consultants and ancillary care providers demonstrate practice consistent with this plan. The nurse ensures that the attending physician is aware of changes in the patient's condition and that interventions are consistent with accepted standards of practice.
2. Hospital systems expertise include organizational leadership, implementation of unit-based protocols, quality improvement expertise, and analysis of data from outcome pathways, staff and patient satisfaction, and sentinel events.

Critical care nurses do the majority of patient assessment, evaluation, and care in the ICU. The ratio of patients to bedside nurses is typically 2:1. This allows the critical care nursing staff to spend several hours per patient per shift collecting and integrating information and incorporating it into meaningful patient care. Through their caring practices, they improve the ICU experience for both patients and their families, and through their critical thinking skills, experienced nurses readily recognize clinical changes to prevent further deterioration in these patients. They are familiar with the complications that may be seen in these patients and attempt to prevent them. When practicing in a multiple consultant model, nurses are often faced with reconciling competing orders and unclear lines of both authority and responsibility for patient care.

An advanced practice nurse (APN) is a nurse who has received education at the graduate level, or higher. APNs provide health care to patients and families and may demonstrate a high level of independence. Advanced practice nurses collaborate with the critical care team in developing and implementing a plan of care that is dynamic. In some ICUs, the APN may alter the plan of care. APNs combine clinical practice with education, research, consultation, and leadership. APNs, including clinical nurse specialists and nurse practitioners, teach and mentor nursing staff, educate patients and families, and create teaching materials for a specific type of patient. Counseling families about the short- and long-term management of a patient's illness is an important component of the practice of an APN.

Pharmacy Component

Appendix 4 and a review by Rudis et al. (39) describe specific details of pharmacists' responsibilities in the ICU. General responsibilities of the pharmacist in the ICU include comprehensive monitoring of medication usage to provide cost-effective pharmacotherapy and to intervene as necessary in the medication delivery process to maximize patient outcomes. The pharmacist and pharmacy services may function from an ICU satellite pharmacy or from centralized pharmacy services. Pharmacists participate in drug therapy evaluations either prospectively (before a medication order) or retrospectively (after the medication order). Based on institutional resources, the pharmacist's responsibility in providing pharmacotherapy services is fulfilled using several different practice models.

In one model, pharmacists retrospectively evaluate medication orders but usually do not attend ICU rounds. In a second model, pharmacists are assigned to a critical care satellite pharmacy, with simultaneous responsibilities including dispensing of medications, prospective evaluation of medication orders, and attending ICU rounds. In a third model, pharmacists are exclusively assigned to direct patient care responsibilities, including attending daily unit rounds, obtaining medication histories, and prospectively evaluating drug therapy. Pharmacist consultative services in pharmacotherapy, nutrition support, or pharmacokinetics may be available as an added service to any of the practice models.

Respiratory Therapy Component

The role of the respiratory care practitioner as an integral member of the ICU clinical team focuses primarily on management of the patient/ventilator system, airway care, delivery of bronchodilators, monitoring of hemodynamics and blood gases, and the delivery of protocol-regulated respiratory care. As outlined below, several trials have demonstrated the importance of respiratory care practitioners in facilitating weaning from mechanical ventilation and improving the allocation of respiratory care services.

Current evidence suggests that respiratory therapist-directed ventilator weaning, via protocol, results in a shorter duration of mechanical ventilation compared with traditional physician-directed weaning. Additional benefits include reduced costs, a decrease in nonlethal complications, and reduced re-intubation rates (21–25). These trials represent prospective, randomized, controlled trials in single institutions using concurrent controls and demonstrate the value of the

integration of respiratory therapy into the healthcare team in the ICU. In addition, resource allocation is improved with respiratory therapist-driven protocols to optimize equipment and personnel utilization (26–30).

OUTCOME DATA—MODELS AND PATTERNS OF CRITICAL CARE PRACTICE

Overall Assessment of the Literature

There are numerous problems associated with evaluation and comparison of the medical literature regarding models and patterns of critical care delivery. Recent literature, focused primarily on the organization of the physician's role at the bedside or unit level, has created disparate views of unit organization. Is there a critical care team? Is the ICU open or closed? Should there be 24-hr in-house coverage? There are often large differences among MICUs, surgical ICUs, and pediatric ICUs. There are differences among highly specialized university hospitals, regional community tertiary facilities, and small to medium nonteaching community hospitals. There are differences between ICUs in cities and in rural settings, as well as in large urban inner-city facilities.

In addition, there are multiple confounding factors, usually not addressed in the literature, that further complicate any analysis of outcomes based on models of critical care practice. These confounding variables include the presence or absence of nonphysician providers, quality, quantity, and type of bedside nursing care, regionalization of medical care, and lack of standard definitions for ICU administrative management. Few studies address differences among various mid-level care providers, such as house staff, fellows, acute care nurse practitioners, physician assistants, critical care nurse specialists, respiratory therapists, pharmacists, and nutritionists. There are few studies dealing with different bedside nursing patterns or personnel composition, such as licensed practical nurses, masters trained nurses, certified critical care nurses, ICUs with stable nursing patterns, those with shortages at night or on weekends, or those that have high use of "traveling" nurses. There are few studies related to regionalization, or remote critical care attending services via telemedicine, or the impact of intermediate care (step-down/progressive care) on ICU outcome data. Measures are not well standardized regarding the evaluation of ICU management that could form the basis of useful comparisons of models of care. These measures should include an organizational assessment of leadership, culture, coordination, communication, conflict management, and team cohesion and perceived unit effectiveness (40). Most standardized outcome measures of severity-adjusted mortality and resource use may not be sensitive to these management measures. Few studies relate ICU models of care to quality-of-life outcomes and patient/family/caregiver satisfaction. For families, continuity of care with previously known and respected physicians would seem important. Also fewer moves while in the hospital would likely lead to high satisfaction scores (41). Despite the aforementioned limitations, there is an emerging literature that addresses ICU outcome and the pattern of practice within the ICU.

Medline-PubMED and the Cochrane Library were searched using the following key words: practice patterns; organizational characteristics; ICU; outcomes assessment; outcome; intensivist; pharmacist; critical care nurse; respiratory therapist. Articles were abstracted for further review if they described outcome assessment attributed to or associated with a model of clinical critical care practice. Examining the bibliography of articles previously abstracted identified additional references. By using this methodology, 143 articles were identified. The following sections summarize the data identified that pertain to outcome and practice patterns of critical care medicine. Some of the studies that describe outcomes associated with specific practitioner types, but within an overall critical care practice model, are discussed separately.

Nonrandomized Studies

There are a number of small, nonrandomized studies primarily using historical controls (level IV) that support the presence of an intensivist in the ICU compared with a prior model without an intensivist. These studies were usually done when there was a change in ICU organizational structure, primarily the addition of an intensivist. ICU outcome data (usually mortality) from a time period before the addition of the intensivist are compared with data for a time period after the addition of the intensivist. These studies suggest that ICU mortality and cost are lower with an intensivist present in the ICU. Although it is tempting to perform a meta-analysis, we do not believe this approach would be productive because of the methodological problems associated with combining multiple studies with design flaws into an analysis with a large number of patients and the same design flaws. We will, however, summarize the findings of many of the individual studies outlined above. Data available only in abstract format have been omitted.

Reynolds NH, Haupt MT, Thill-Baharozian MC, et al: Impact of critical care physician staffing with septic shock in a university hospital medical intensive care unit. *JAMA* 1988; 260:3446–3450 (42) (level IV evidence)

In a retrospective review of MICU records, two consecutive 12-month periods of time were compared. During the first time period, the ICU was without critical care-trained faculty, and during the second time period, the ICU was supervised by critical care-trained faculty. Severity of illness scores were comparable during the two time periods. Mortality was significantly decreased during the postcritical care medicine time period.

Pollack MM, Katz RW, Ruttimann UE, et al: Improving the outcome and efficiency of intensive care: The impact of an intensivist. *Crit Care Med* 1988; 16:11 (14) (level IV evidence)

This article was a retrospective review of PICU records comparing two time periods with and without an intensivist. A greater use of therapeutic monitoring and favorable effects on bed utilization occurred during the intensivist time period. No effect on mortality or length of stay was demonstrated.

Brown JJ, Sullivan G: Effect on ICU mortality of a full-time critical care specialist. *Chest* 1989; 96:127–129 (43) (level IV evidence)

A retrospective review was conducted of two time periods (consecutive years) in a MICU, before and after the addition of a trained critical care specialist (intensivist). Despite similar severity of illness, the mortality rate was significantly lower during the intensivist time period.

Baggs JG, Ryan SA, Phelps CE, et al: The association between interdisciplinary collaboration and patient outcomes in a medical intensive care unit. *Heart Lung* 1992; 21:18–24 (44) (level IV evidence)

A prospective survey of nurses and residents in a MICU was conducted regarding their view of collaboration at the time of ICU discharge. The nurse's report of collaboration (nonvalidated survey tool) was positively correlated with patient outcome after controlling for severity of illness.

Pollack MM, Cuerdon TT, Patel KM, et al: Impact of quality of care factors on pediatric intensive care unit mortality. *JAMA* 1994; 272:941–946 (45) (level III evidence)

Data were collected from a national survey of 16 representative pediatric ICUs. The ICUs differed significantly with respect to descriptive statistics. Risk-adjusted mortality data indicated that the presence of a pediatric intensivist was significantly associated with improved patient survival. The presence of pediatric residents was associated with an increased mortality risk. The conclusions in this study have been challenged because of the diverse nature of the ICUs studied.

Carson SS, Stocking C, Podsadecki T, et al: Effects of organizational change in the medical intensive care unit of a teaching hospital: A comparison of 'open' and 'closed' formats. *JAMA* 1996; 276:322–328 (13) (level III evidence)

This was a prospective cohort study that examined two consecutive time periods of ICU care. The first encompassed an open ICU organizational structure, wherein critical care specialists consulted on all ICU patients and made recommendations, but the admitting attending physician retained primary responsibility for patient care. Under the closed format, the critical care attending physician assumed primary responsibility for all patient care and the admitting physician was a consultant. Despite significantly higher severity of illness scores during the closed ICU organization, the risk-adjusted mortality score was 0.78 compared with 0.90 in the open ICU organization. Resource utilization did not increase during the closed unit structure, despite higher severity of illness.

Pollack MM, Patel KM, Ruttimann UE, et al: Pediatric critical care training programs have a positive effect on pediatric intensive care mortality. *Crit Care Med* 1997; 25:1637–1642 (46) (level IV evidence)

This was a cohort study of 16 volunteer PICUs (eight with PICU fellowships and eight without fellowships). Pediatric ICUs with fellowship training programs had better risk-adjusted mortality rates compared with those without training programs.

Rosenthal GE, Harper DL, Quinn LM, et al: Severity adjusted mortality and length of stay in teaching and nonteaching hospitals: Results of a regional study. *JAMA* 1997; 278:485–490 (47) (level IV evidence)

This was a retrospective cohort study examining 30 hospitals in Ohio. Risk-adjusted mortality and length of stay were lower in teaching hospitals compared with nonteaching hospitals.

Manthous CA, Amoateng-Adjepong Y, Al-Kharrat T, et al: Effects of medical intensivist on patient care in a community teaching hospital. *Mayo Clin Proc* 1997; 72:391–399 (48) (level IV evidence)

This was a retrospective review of MICU patient admissions comparing two consecutive time periods before and after the addition of a medical intensivist. Patient severity of illness was similar during the two time periods. Mortality for pneumonia, mean length of hospital stay, and MICU stay were all reduced after the addition of the medical intensivist.

Multz, AS, Chalfin DB, Samson IM, et al: A closed medical intensive care unit (MICU) improves resource utilization when compared with an open MICU. *Am J Respir Crit Care Med* 1998; 157: 1468–1473 (49) (level IV evidence)

A complicated methodology was used, wherein a retrospective analysis of two time periods in one hospital was compared as the ICU administrative structure changed from an open organizational structure to a closed one (retrospective analysis). In addition, another cohort of patients was prospectively analyzed, wherein one group from one hospital managed in an open ICU organizational structure was compared with another group from another hospital managed in a closed ICU organizational structure (prospective analysis). Illness severity and primary diagnostic categories between groups were comparable. ICU and hospital length of stay was less in closed units. An open ICU format was associated with greater mortality prediction.

Ghorra S, Reinert SE, Cioffi W, et al: Analysis of the effect of conversion from open to closed surgical intensive care unit. *Ann Surg* 1999; 229:163–171 (50) (level IV evidence)

This is a retrospective review comparing two time periods (open unit vs. closed unit) in a surgical ICU. Mortality and overall complications were significantly higher in the open-unit group compared with the closed-unit group.

Cole L, Bellomo R, Silvester W, et al: A prospective, multicenter study of the epidemiology, management, and outcome of severe acute renal failure in a "closed" ICU system. *Am J Respir Crit Care Med* 2000; 162:191–196 (51) (level III evidence)

This was a prospective, observational study examining the outcome of acute renal failure requiring replacement therapy (severe acute renal failure) within closed ICU systems in Australia. The study was conducted over a 3-month period in all nephrology units and ICUs in the state of Victoria (all closed ICUs with critical care physicians in charge of all patients), Australia. Demographic, clinical, and outcome data using standardized case report forms were collected. By using the SAPS II score or a recently validated renal-failure specific score, the predicted mortality for these patients was shown to be 59%. Actual mortality was 49.2%. The authors concluded that patients with renal failure managed in closed ICU systems in Australia had favorable outcomes compared with predicted mortality.

Blunt MC, Burchett KR: Out-of-hours consultant cover and case-mix-adjusted mortality in intensive care. *Lancet* 2000; 356:735–736 (52) (level IV evidence)

A historical case control study examined standardized mortality ratios in 452 patients admitted to an ICU after an intensivist joined the staff compared with 372 patients before the intensivist's arrival. Severity of illness scores were comparable in both groups; however, the standardized mortality ratio improved significantly in the intensivist group (0.81 vs. 1.11; ratio, 0.73 [95% confidence interval, 0.55–0.97]).

Practitioner-Specific Studies

Mitchell P, Armstrong S, Simpson T, et al: American Association of Critical Care Nurses Demonstration Project: Profile of excellence in critical care nursing. *Heart Lung* 1989; 18:219–226 (53) (level IV evidence)

This study demonstrated that improved patient outcomes were associated with nurse staffing levels, nurse credentials, model of nursing care delivery, a model of shared or participative governance, and the degree of collaboration between nursing and medicine.

Tarrow-Mordi WG, Hau C, Warden A, et al: Hospital mortality in relation to staff workload: A 4-yr study in an adult intensive care unit. *Lancet* 2000; 356: 185–189 (20) (level IV evidence)

This article describes a 4-yr study of all admissions to an adult ICU in the United Kingdom, wherein adjusted mortality was more than two times higher when the nursing workload was higher compared with when it was lower.

Montazeri M, Cook DJ: Impact of a clinical pharmacist in a multidisciplinary intensive care unit. *Crit Care Med* 1994; 22:1044–1048 (19) (level III evidence)

This prospective observational study describes pharmacist interventions during a 3-month period in a medical-surgical ICU. During the study, there were 10.7 ± 5.0 pharmacist interventions per day. These interventions included providing drug information to physicians and nurses, drug order clarification, pharmacokinetic information, and adverse reaction reporting. The pharmacist-initiated therapeutic interventions resulted in significantly reduced drug costs ($67,664.24 annualized) compared with historical controls.

Overall Best Studies in the Literature

Pronovost PJ, Jenckes MW, Dorman T, et al: Organizational characteristics of intensive care units related to outcomes of abdominal aortic surgery. *JAMA* 1999; 281:1310–1317 (54) (level III evidence)

This is a large observational, nonrandomized study using contemporaneous controls. The study was done using the Maryland Health Discharge Data Set, with a focus on patients undergoing major abdominal aortic surgery (n = 2987). The study compiled data from 39 of 46 acute care hospitals in the state of Maryland. The authors used a multitiered, multivariable analytic technique and showed that daily rounds in the ICU by an ICU physician was associated with reduced in-hospital mortality and specific postoperative medical complications. The magnitude of this mortality reduction was equivalent to that observed in other studies that compared the skill (and surgical volume) of operating surgeons. The authors used a validated survey instrument, completed by the ICU medical director of participating ICUs, to define physician organizational characteristics. There was a significant association between reduced nurse-patient staffing on the day and evening shifts and increased resource use as estimated by increased ICU and hospital days. There are at least two concerns with this study. One is that the authors could not detect a difference in mortality based on surgeon operating volume, an association that has been repeatedly shown in many other studies. The second is that even in complex studies, there is usually a suggestion of the final results found in the univariate or demographic tables. In this study, the descriptive tables and the univariate analyses presented did not seem to yield obvious or even subtle clues regarding what was ultimately shown with the multilevel technique. The authors concluded that daily rounds by an ICU physician reduce mortality and complications in the patient population studied.

Leape LL, Cullen DJ, Demspey Clapp M, et al: Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. *JAMA* 1999; 282: 267–270 (18) (level II evidence)

This is a controlled clinical trial examining the incidence of preventable adverse drug events before and after the introduction of a senior clinical pharmacist (intervention) to the daily rounds in the MICU. A medical coronary care unit was used as a control unit. Preventable adverse drug events (attributable to prescribing errors) decreased by 66% after the intervention, whereas there was no change in the rate of prescribing type drug errors in the control unit.

Knaus WA, Draper EA, Wagner DP, et al: An evaluation of outcome from intensive care in major medical centers. *Ann Intern Med* 1986; 104:410–418 (55) (level III evidence)

This study is the *post hoc* analysis of the original Acute Physiology and Chronic Health Evaluation (APACHE) II database. This study was a large, nonrandomized observational study. There were 13 hospitals and 5,030 patients used to develop the APACHE II severity of illness system. The authors rank ordered the hospital ICUs by the actual or observed mortality and the predicted hospital deaths. The ICUs' medical or nursing director completed a detailed questionnaire regarding staffing, organization, policies, procedures, and extent of the critical care personnel's participation in patient care. The use of risk stratification with the standardized mortality ratio demonstrated there were differences in the organizational patterns that supported the hypothesis that the degree of coordination of intensive care services significantly influenced its effectiveness. The organizational patterns were related to both the medical and nursing components. The rank ordering did not include a confidence interval, and it is likely that the statistical difference was primarily between the top hospital and the bottom hospital. The top ICU was well organized, with protocols and policies including the cancelling of elective operating room cases if no beds were available. There was also a high proportion of bedside nurses who had master's degree. In addition, there were no interns (postgraduate year-1) in this unit. The bottom hospital did not have an organized medical program and had a substantial shortage of nursing. There was an atmosphere of distrust, and there was no coordination of care. The APACHE III study with a larger sample size and some attempt at enrolling representative hospitals was not able to confirm the relationship between management coordination and collaboration and severity-adjusted mortality outcomes. These analyses are problematic because it is difficult to evaluate the management components of care in an objective way. It is concluded that organized ICUs as defined in this review had lower mortality.

Hanson CW, Deutschman CS, Anderson HL, et al: Effects of an organized critical care service on outcomes and resource utilization: A cohort study. *Crit Care Med* 1999; 27:270–274 (56) (level III evidence)

This study compared two different concurrent care models of surgical ICU patients. One group was managed exclusively by the critical care attending service and the other by the general surgical faculty and house staff. Despite higher severity of illness scores, the critical care patient group had shorter ICU lengths of stay, fewer days of mechanical ventilation, fewer arterial blood gases, fewer consultations, fewer complications, shorter hospital lengths of stay, and fewer Medicare-adjusted charges. The critical care service model in this surgical ICU demonstrated improved quality and cost.

Pronovost et al. (57), in a recent systematic review of the available literature regarding ICU physician staffing and outcomes, concluded that there is a consistent finding of decreased mortality and length of stay with intensivist presence. Despite the aforementioned data, there is no randomized, prospective trial that effectively compares outcome between var-

ious models of critical care delivery. In an editorial in *Critical Care Medicine*, Hall (58) questions the interpretation of the currently available outcome data. He notes that even if the differences are real, it remains unclear which components of care have resulted in the observed effects. He further suggests that future multicentered trials are clearly required.

WHAT IS THE BEST PRACTICE MODEL?

The analysis of any model of critical care delivery should be based on its ability to minimize mortality and to optimize efficiency while preserving dignity and compassion for patients. Current literature, although not clearly identifying a "best" practice model, does identify factors that are related to improved outcome as measured by reduced mortality, improved efficiency, decreased length of stay, or decreased cost of care. These are as follows.

- Timely and personal intervention by an intensivist reduces mortality, reduces length of stay, and decreases cost of care.
- In academic centers, the addition of an intensivist to the critical care team reduces mortality. It is not clear from the existing literature that 24-hr full-time presence of an intensivist vs. an 8–12 hr day is superior to having access to the intensivist in a "timely period." Further research may clarify this point.
- When an intensivist is available in an administrative role in the ICU providing benchmarking, clinical research, and standardization of care, the data suggest that length of stay, cost of care, and treatment complications can be reduced.
- The presence of a critical care pharmacist can decrease adverse drug events and reduce cost of care.
- Excessive nursing workload, as defined by hours per patient day or nurse/patient ratios, is associated with increased mortality in critically ill patients.
- The presence of full-time respiratory care practitioners dedicated to the ICU can reduce length of ICU stay, shorten ventilator days, and reduce overall ICU costs.

RECOMMENDATIONS AND CONCLUSIONS

The literature does not clearly support one model of critical care delivery over another; however, it does support a recommendation for a model wherein dedicated ICU personnel, specifically the intensivist, the ICU nurse, respiratory care practitioner, and pharmacist, all work as a team. Furthermore, this multidisciplinary group practice model should be led by a full-time critical care-trained physician who is available in a timely fashion to the ICU 24 hrs per day (grade D recommendation).

While leading the critical care service, the intensivist physician should have no competing clinical responsibilities (grade E recommendation).

ICUs with an exclusive critical care service and operating in the closed format, as described previously, may have improved outcomes. When geographic constraints, resource limitations, and manpower issues allow, this organizational structure for the delivery of critical care services may be optimal (grade E recommendation).

The presence of a pharmacist as an integral part of the ICU team, including but not limited to making daily ICU rounds, improves the quality of care in the ICU and reduces errors. The integration of a dedicated pharmacist into the ICU team is recommended (grade C recommendation).

Physician practitioners in the ICU should have hospital credentials to practice critical care medicine. These credentials should incorporate both cognitive and procedural competencies (expert opinion).

Additional study is crucial. Multicenter trials must be designed to answer questions regarding what aspects of care are crucial to improved outcome. To what extent does administrative or protocol implementation make a difference? Are complications reduced as a result of critical care team involvement? Does additional expertise immediately available at the bedside provide the fundamental effect to improve outcome?

The SCCM research committee should organize a multicentered, prospective trial, possibly in conjunction with other organizations, such as the American Thoracic Society or the National Institutes of Health (NIH), to answer some of the aforementioned questions. A NIH consensus panel, similar to that organized for the use of pulmonary artery catheters, may also be appropriate. As outlined at the outset, it is imperative that critical care practitioners define what constitutes ICU quality, how it should be measured, and delivered by what practice model.

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APPENDIX 1

Grading of Levels of Evidence and Recommendations

Grading of recommendations

A = Supported by at least two level I investigations

B = Supported by only one level I investigation

C = Supported by level II investigations only

D = Supported by at least one level III investigation

E = Supported by level IV or level V evidence

Levels of evidence

Level I = Large, randomized trials with clear-cut results; low risk of false-positive (α) error or false-negative (β) error

Level II = Small, randomized trials with uncertain results; moderate to high risk of false-positive (α) and/or false-negative (β) error

Level III = Nonrandomized, concurrent cohort comparisons, contemporaneous controls

Level IV = Nonrandomized, historical cohort comparisons/controls, and expert opinion

Level V = Case series, uncontrolled studies, and expert opinion

APPENDIX 2

The Intensivist

This definition of an intensivist refers to physician credentials (1), process and focus on care (2, 6, 7, 9, 10), scope of expertise (3, 4), availability (5, 6), and professional responsibility (8). An intensivist is as follows.

1. A physician who is trained and certified through a primary specialty and has successfully completed an Accreditation Council for Graduate Medical Education-approved training program in critical care medicine and/or has a certificate of special qualification in critical care.
2. Diagnoses, manages, monitors, intervenes, arbitrates, and individualizes the care to each patient at risk for, in the midst of, or recovering from critical illness.
3. Has the training and skills to manage patients with multiple health problems derived from multiple causes. These skills range on the continuum of care from acute resuscitation to management through the recovery phase of illness, including but not limited to the following.
   a. Hemodynamic instability, cardiac failure, and cardiac dysrhythmias
   b. Respiratory insufficiency or failure, with or without a need for mechanical ventilatory support
   c. Acute neurologic insult, including treatment of intracranial hypertension
   d. Acute renal failure or insufficiency
   e. Acute life-threatening endocrine and/or metabolic derangement
   f. Drug overdoses, drug reactions, and poisonings
   g. Coagulation disorders
   h. Serious infections
   i. Nutritional insufficiency requiring nutritional support
   j. End-of-life issues

Management of patients in the immediate perioperative period is as follows.

4. Is able to perform, manage, and coordinate the need for certain procedures including, but not limited to the following.
   a. Maintenance of the airway including tracheal intubation and mechanical ventilation
   b. Placement of intravascular catheters and monitoring devices including the following
      1) Arterial catheters
      2) Central venous catheters
      3) Pulmonary artery catheters
      4) Temporary dialysis catheters
   c. Placement and maintenance of temporary pacing devices
   d. Cardiopulmonary resuscitation
   e. Tube thoracostomy
   f. Other procedures that intensivists may perform include therapeutic bronchoscopy, percutaneous tracheostomy, transesophageal echocardiography, renal replacement therapy, cricothyroidotomy, EEG, and placement of intra-aortic balloon counterpulsation device.
5. Is immediately and physically available to patients in the ICU and has no competing priority that would interfere with the prompt delivery of critical care during scheduled intervals while acting as the clinical intensivist.
6. Participates in a unit-based, hospital-approved coverage system that provides 24 hr a day availability by physicians who possess similar credentials in critical care.
7. Promotes quality and humane care in the ICU while maintaining efficient use of resources.
8. Furthers the practice of critical care medicine through education of colleagues and the public.
9. Provides unit-based administrative duties that include but are not limited to the following
   a. Admission/discharge decisions
   b. Treatment protocol development and implementation
   c. Supervising and directing performance improvement activities
   d. Maintaining up-to-date equipment and techniques
   e. Responsible for unit-based data collection
   f. Promulgate links to other ancillary departments that are involved in the care of the ICU patient, e.g., pharmacy, radiology, infection control, social and pastoral care, etc.
   g. Responsible for approval of unit-based budget
10. Responsible for coordinating educational needs for unit-based as well as general hospital personnel and the public

APPENDIX 3

The Critical Care Nurse

The American Association of Critical Care Nurses (AACN) provided much of the summary outlined below.

1. Is a licensed professional who is responsible for ensuring that all acutely and critically ill patients receive optimal nursing care. Basic to the provision of optimal care is individual professional accountability through adherence to standards of nursing care of acutely and critically ill patients and a commitment to act in accordance with ethical principles.
2. Clinical nursing practice varies considerably depending on the setting in which nurses are employed and the patient population for which they provide care. The American Association of Critical Care Nurses *Standards for Acute and Critical Care Nursing Practice* provides the foundation for a minimum level of competent and professional care delivered to critically ill patients in a variety of settings. Broad application of these standards by critical care nurses is expected to help promote quality care and positive patient outcomes.
3. Standards of care for acute and critical care nursing are as follows.
   a. Assessment: The nurse caring for the critically ill patient collects relevant patient health data.

b. Diagnosis: The nurse caring for critically ill patients analyzes the assessment data in determining diagnoses.
c. Outcome identification: The nurse caring for the critically ill patient identifies individualized, expected outcomes for the patient.
d. Planning: The nurse caring for the critically ill patient develops a plan of care that prescribes interventions to attain expected outcomes.
e. Implementation: The nurse caring for the critically ill patient implements interventions identified in the plan of care.
f. Evaluation: The nurse caring for the critically ill patient evaluates the patient's progress toward attaining expected outcomes.

4. Standards of Professional Practice are as follows.
   a. Quality of care: The nurse caring for the critically ill patient systematically evaluates the quality and effectiveness of nursing practice.
   b. Individual practice evaluation: The nurse's practice reflects knowledge of current professional standards, laws, and regulations.
   c. Education: The nurse acquires and maintains current knowledge and competency in the care of critically ill patients.
   d. Collegiality: The nurse caring for the critically ill patient interacts with and contributes to the professional development of peers and other healthcare providers as colleagues.
   e. Ethics: The nurse's decision and actions on behalf of critically ill patients are determined in an ethical manner.
   f. Collaboration: The nurse caring for the critically ill patient collaborates with the team of patient, family, and healthcare providers in providing patient care in a healing, humane, and caring environment.
   g. Research: The nurse caring for the critically ill patient uses clinical inquiry in practice.
   h. Resource utilization: The nurse caring for the critically ill patient considers factors related to safety, effectiveness, and cost in planning and delivering patient care.

5. Certification is voluntary through the AACN Certification Corporation. The certified nurse receives a CCRN credential available for nurses who care for adults and pediatric and neonatal patients.

APPENDIX 4

The ICU Pharmacist

1. Is a practitioner who is licensed by the State Board of Pharmacy and has specialized training or practice experience providing pharmaceutical care for the critically ill patient.
2. In providing pharmaceutical care is responsible for administering the following services.
   a. Evaluation of all drug therapy for appropriate indication, dose, route, and dosage form
   b. Evaluation of all drug therapy to avoid drug, food, and nutrient allergies and interactions
   c. Evaluation of all drug therapy to maximize cost-effectiveness
   d. Monitoring all drug regimens for efficacy
   e. Monitoring all drug regimens for toxicity and recommending methods for preventing toxicity
   f. Detects, evaluates, and reports all adverse drug events
   g. Interviewing patients and their caregivers to obtain an accurate medication history
   h. Evaluation of all enteral and parenteral nutrition orders for appropriateness
   i. Providing pharmacokinetic monitoring and consultation
   j. Providing drug information, intravenous compatibility information, and poison information
   k. Educating the ICU team members on pharmacotherapy issues
3. Documents pertinent pharmaceutical care recommendations in the medical record.
4. Participates on various institution committees that involve drug-related issues in the critically ill, such as pharmacy and therapeutics, intensive care committee, adverse drug reactions, and advanced cardiac life support.
5. Participates in medication use evaluations and quality assurance activities.
6. Coordinates the development and implementation of drug-related policy, procedures, guidelines, protocols, and pathways.
7. Collaborates with medical and nursing staff in research endeavors.

APPENDIX 5

The ICU Respiratory Care Practitioner

1. Is a practitioner who is licensed by the State Respiratory Care Board (if applicable) and has specialized training or practice providing cardiorespiratory care for critically ill patients.
2. In providing cardiorespiratory care, the respiratory therapist is responsible for the following services.
   a. Evaluation of respiratory therapy orders for appropriate indication, medication, equipment, and potential efficacy
   b. Evaluation of orders for mechanical ventilatory support for appropriate indication and implementation
   c. Evaluation of all respiratory therapy procedures to maximize efficacy and cost-effectiveness
   d. Monitoring of mechanical ventilatory support to minimize complications and maximize therapeutic goals and to enhance patient comfort
   e. Monitoring of respiratory care procedures for improving efficacy, reducing adverse effects, and assuring safety
   f. Detects, evaluates, and reports all adverse events related to mechanical ventilation and respiratory care procedures
   g. Provides consultation on mechanical ventilation, respiratory therapy procedures, weaning from ventilatory support, delivery of aerosolized medications, airway management, and novel treatments
   h. Educates the ICU team members on issues related to mechanical ventilation and respiratory care procedures
3. Documents pertinent respiratory care recommendations in the medical record.
4. Participates on institution committees that involve respiratory care and mechanical ventilation issues, such as the cardiopulmonary resuscitation committee, pharmacy and therapeutics, and intensive care quality assurance committee.
5. Coordinates the development and implementation of respiratory care and mechanical ventilation procedures, guidelines, protocols, and pathways.

6. Collaborates with medical staff in research endeavors.
7. Respiratory care services should be available 24 hrs a day, 7 days a week.

APPENDIX 6

Members of the ACCM Task Force on Models of Critical Care Delivery

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APPENDIX 7

ACCM Guidelines for the Definition of an Intensivist and the Practice of Critical Care Medicine

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A Prospective, Controlled Trial of a Protocol-based Strategy to Discontinue Mechanical Ventilation

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Weaning protocols can improve outcomes, but their efficacy may vary with patient and staff characteristics. In this prospective, controlled trial, we compared protocol-based weaning to usual, physician-directed weaning in a closed medical intensive care unit (ICU) with high physician staffing levels and structured, system-based rounds. Adult patients requiring mechanical ventilation for more than 24 hours were assigned to usual care (UC) or protocol weaning based on their hospital identification number. Patients assigned to UC (n = 145) were managed at their physicians' discretion. Patients assigned to protocol (n = 154) underwent daily screening and a spontaneous breathing trial by respiratory and nursing staff without physician intervention. There were no significant baseline differences in patient characteristics between groups. The proportion of patients (protocol vs. UC) who successfully discontinued mechanical ventilation (74.7% vs. 75.2%, p = 0.92), duration of mechanical ventilation (median [interquartile range]: 60.4 hours [28.6–167.0 hours] vs. 68.0 hours [27.1–169.3 hours], p = 0.61), ICU (25.3% vs. 28.3%) and hospital mortality (36.4% vs. 33.1%), ICU length of stay (115 vs. 146 hours), and rates of reinstituting mechanical ventilation (10.3% vs. 9.0%) was similar. We conclude that protocol-directed weaning may be unnecessary in a closed ICU with generous physician staffing and structured rounds.

Keywords: ventilator weaning; respirator, artificial; critical care; nursing care

Several recent randomized trials and prospective case series have found that protocols directed by nursing and respiratory care staff can expedite the discontinuation of mechanical ventilation (1–12). Because mechanical ventilation commonly necessitates intensive care unit (ICU) care, these findings could improve both patient outcomes and resource use. A recent evidence-based report recommended more widespread use of such protocols to expedite discontinuation of mechanical ventilation in ICU patients (13), based on a small number of prospective, randomized trials (3, 5, 6).

However, although the outcome benefits of protocols have received wide attention, their limitations are less often acknowledged. Protocols demand substantial resources to design, implement, promote, and sustain their use, without which they may be rapidly abandoned (14). Structural changes such as administratively closed ICUs (15), higher levels of intensivist physician staffing (16), or checklists to make rounds more systematic (17) may also improve clinical outcomes of critically ill patients. It is not known whether weaning protocols retain their ability to speed weaning when such structural changes are in place. If protocols speed the discontinuation of mechanical ventilation only by enforcing daily attention to patients' readiness to breathe unassisted, they may be unnecessary in ICUs in which other structural or practice patterns encourage the same degree of vigilance.

Therefore, the primary objective of this clinical trial was to evaluate whether a protocol for discontinuation of mechanical ventilation, based on a strategy previously shown to be effective (3), accelerates discontinuation of mechanical ventilation compared with usual care (UC) in a closed, academic intensivist–run medical ICU with high physician staffing levels and structured, system-based rounds. Some of these results have been presented in abstract form (18).

METHODS

Detailed methods are available in an online supplement. The medical ICU is a closed 14-bed unit staffed by 2 attendings and 10 M.D. trainees. The physicians work in two teams of six, each team caring for half the patients. All attend structured daily bedside rounds lasting approximately 3 hours. Presentations on rounds are based on a printed template covering each major physiologic system, which is completed by the house staff daily (*see* online supplement). Most physicians remain in the ICU for the workday, and three house officers stay overnight. The nurse (all registered nurses) to patient ratio is 1:2, plus one to two additional senior nurses and one to two respiratory therapists. The staff is experienced with numerous protocols guiding nonventilatory care and has used ventilator protocols in patients enrolled in the Acute Respiratory Distress Syndrome Network studies (19).

All patients requiring invasive ventilation for 24 hours or more from April 2000 to July 2001 were eligible. Previous participants, those enrolled in other studies that controlled weaning (such as the ARDS Network studies) or transferred from other facilities already intubated, were excluded. The institutional review board waived the requirement for informed consent.

Patients were assigned to a study group by their hospital numbers (odd versus even). The protocol wean (PW) was based on one previously shown to reduce duration of ventilation (3). This consisted of a daily screen for readiness, followed by measurement of the ratio of respiratory frequency to mean V_T (f/V_T) in patients passing the screen. If f/V_T was 105 or less, a spontaneous breathing trial (SBT) was then attempted on continuous positive airway pressure (CPAP), with 5 cm H_2O pressure support added if the endotracheal tube was 7 mm or less. Physicians were told whether the SBT was tolerated for 1 hour. If not, the patient was rested on mechanical ventilation until the next morning (Table 1). Physicians could also extubate PW patients based on their clinical judgment. Staff were trained in the protocol, which was piloted during a 2-month run-in period. For patients randomized to UC, discontinuation of ventilation was left entirely to the discretion of the physicians. No scheduled screening was performed by ancillary staff, although an f/V_T determination could be requested or measured by the attending at the bedside. Physicians specified each ventilator setting or the beginning and end of a SBT with an individual order. Routine care included a sedation protocol titrating midazolam and/or fentanyl to a behavioral goal.

The ICU fellow documented the reason for intubation and presence of chronic respiratory disease on case report forms. A study coordinator contemporaneously reviewed and reinforced staff compliance.

Data on weaning methods were not collected contemporaneously on patients in the UC arm. After completion of the study, a random sample of 50 patient charts in this group was reviewed to extract data

(*Received in original form June 9, 2003; accepted in final form January 7, 2004*)

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This article has an online supplement, which is accessible from this issue's table of contents online at www.atsjournals.org

Am J Respir Crit Care Med Vol 169. pp 673–678, 2004
Originally Published in Press as DOI: 10.1164/rccm.200306-761OC on January 15, 2004
Internet address: www.atsjournals.org

TABLE 1. FAILURE CRITERIA FOR SCREENING FOR SPONTANEOUS BREATHING TRIAL AND FOR THE TRIAL ITSELF

Screening for f/VT
- Patient is not advanced to f/VT measurement if any of the following are present:
  - Known or suspected increased intracranial pressure
  - Unstable coronary artery disease
  - Heart rate ≥ 140 bpm
  - Wean screen prohibited by physician
  - Sp_{O_2} < 92%
  - PEEP > 5 cm H_2O
  - FI_{O_2} > 0.5
  - Receiving paralytics
  - Absent cough and gag reflex
  - Unresponsive to noxious stimuli

SBT (performed if screen for f/VT passed and f/VT < 106)
- Patient is returned to ventilator if within 1 hr of initiating SBT any of the following occur:
  - Heart rate > 20 bpm above rate before initiating SBT, persisting for > 5 min
  - Systolic blood pressure < 90 torr (12 kPa) or > 30 torr (4 kPa) change after initiating SBT, persisting > 5 min
  - Chest pain or ECG changes (ischemia or new arrhythmia)
  - Sp_{O_2} < 88% or Pa_{O_2} < 60 torr (8 kPa), persisting > 5 min
  - Marked distress, dyspnea, or agitation

Definition of abbreviations: f/VT = frequency to mean VT; PEEP = positive end-expiratory pressure; SBT = spontaneous breathing trial; Sp_{O_2} = pulse oximetric measurement of arterial oxygen saturation.

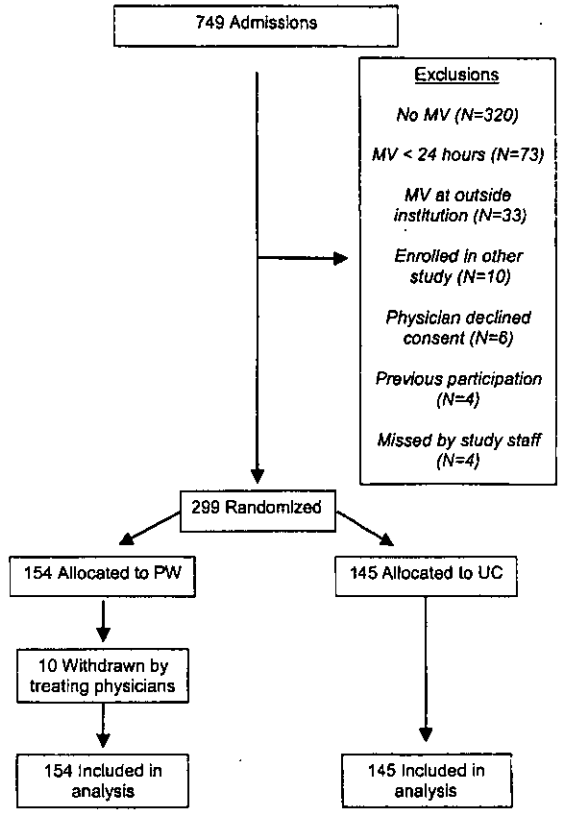

Figure 1. Patient-flow diagram. MV = mechanical ventilation; PW = protocol-directed MV discontinuation; UC = usual care (traditional, physician-directed MV discontinuation).

on weaning methods. Because measurement of f/VT was not routinely performed or documented in the UC group, these data are unavailable.

Data are presented as mean ± SD, median (interquartile range), or proportions, as appropriate. The primary outcome was duration of ventilation, defined as the time from intubation to the beginning of the SBT that ended with successful discontinuation of mechanical ventilation. Patients were considered to have successfully weaned if they were able to breathe unassisted for 48 hours. Compliance with the protocol was evaluated by review of the weaning documentation form used by the therapists and nurses and chart review. Analyses were based on intention to treat, with χ^2 tests or Fisher's exact tests and t tests or Wilcoxon-rank sum tests, as appropriate. Multivariable linear regression evaluated the sensitivity of results to imbalances in patient baseline characteristics; p values of more than 0.05 were considered nonsignificant. The sample size provided 82% power (assuming two-sided type I error = 0.05) to detect a 1-day difference in mechanical ventilation duration. Computations were performed using STATA 7.0 (StataCorp LP, College Station, TX).

RESULTS

During the study period, there were 749 admissions to this ICU, of which 356 (47.5%) required invasive mechanical ventilation for at least 24 hours and hence were eligible to participate. Among the excluded patients, 320 were not intubated or ventilated, and 73 were extubated or died in less than 24 hours. Fifty-three patients who were intubated and ventilated for more than 24 hours were excluded for the reasons shown in Figure 1 (33 because of having been transferred from another institution already intubated). Four other potential subjects were missed. Two hundred ninety-nine patients were enrolled. One hundred fifty-four were assigned to the protocol strategy, and 145 to usual physician-directed weaning. Baseline characteristics of the participants are shown in Table 2. There were no significant differences between treatment groups in regards to age, sex, ethnicity, severity of illness on ICU admission (Simplified Acute Physiology Score II score), oxygenation (Pa_{O_2}/FI_{O_2}), or presence of chronic respiratory disease. Patients assigned to PW were less likely to be admitted from another ICU (7.1% vs. 12.4%) or hospital (2.0% vs. 5.5%) or nursing home (1.3% vs. 2.1%) and were more likely to have pneumonia/acute lung injury on initiating mechanical ventilation (33.2% vs. 21.4%), although overall differences between groups in source of admission and reason for initiating mechanical ventilation were not significant (p = 0.27 and p = 0.29, respectively).

Compliance with the protocol was high among the 154 patients assigned to PW. Screening was performed on 743 of 863 patient-days (86.1%) of mechanical ventilation, with 130 patients (84.4%) screened every day when they were on mechanical ventilation. Of the 406 patient-days on which all the screening criteria were passed, 343 (84.5%) were followed by a 1-minute chronic obstructive pulmonary disease trial. Among the 223 patient-days on which f/VT was 105 or less, patients were advanced to a SBT in 88.3% of cases. Ten patients were withdrawn from the PW by their treating physicians, with three (30%) of them dying before ICU discharge.

In the intention-to-treat analyses, there was no difference between groups (PW vs. UC) in the number of patients who successfully discontinued mechanical ventilation before ICU discharge (115 [74.7%] vs. 109 [75.2%], p = 0.92) or their duration of mechanical ventilation (median [interquartile range]: 60.4 hours [28.6–167.0 hours] vs. 68.0 hours [27.1–169.3 hours], p = 0.61; Figure 2). There was no significant advantage to the protocol-based strategy in reducing the time to discontinuing mechanical ventilation even after adjusting for differences in the source of admission and reason for initiating mechanical ventilation at baseline (multivariable linear regression model: reduction in me-

TABLE 2. BASELINE PATIENT CHARACTERISTICS BY GROUP

Characteristic	PW (*n* = 154)	UC (*n* = 145)	p Value
Age, yr, mean ± SD	52.2 ± 7.6	54.5 ± 16.7	0.52
Female, %	52.6	53.1	0.93
Ethnicity, %			
African American	68.8	62.8	0.31
White	26.6	34.5	
Asian	2.6	0.7	
Other	2.0	2.1	
Source of admission, %			
Emergency department	52.0	47.6	0.27
In-patient floor	28.6	22.8	
Other ICU	7.1	12.4	
Intermediate care unit	6.5	4.8	
Other hospital	2.0	5.5	
Nursing home	1.3	2.1	
Other	2.6	4.8	
Reasons for initiating mechanical ventilation, %			
Cardiopulmonary arrest	11.0	12.4	0.29
Pneumonia/acute lung injury	33.2	21.4	
COPD/asthma exacerbation without infiltrates on chest X-ray	9.7	10.3	
Cardiogenic pulmonary edema	5.2	4.1	
Neurologic emergency	16.9	19.3	
Other	24.0	32.4	
SAPS II score, mean ± SD	51.9 ± 18.5	51.2 ± 16.0	0.72
SAPS II predicted hospital mortality, %	50.5	48.8	0.77
Pa_{O_2}/Fi_{O_2}, first 24 hr of ICU stay, median (IQR)*	148 (94–238)	157 (92–228)	0.64
Chronic respiratory disease, %	25.3	31.0	0.27

Definition of abbreviations: COPD = chronic obstructive pulmonary disease; ICU = intensive care unit; IQR = interquartile range; PW = protocol wean; SAPS II = Simplified Acute Physiology Score II; UC = usual care.

* Recorded in patients who required mechanical ventilation within the first 24 hours of ICU stay (UC: 133/154, PW: 129/145).

chanical ventilation time in the PW group = 0.84 hours, p = 0.26). The duration of the SBT preceding successful discontinuation of mechanical ventilation was longer among patients assigned to PW compared with UC (median, 3.0 vs. 1.6 hours, $p < 0.01$; Table 3). There were no significant differences (PW vs. UC) in the number of patients requiring reinstitution of mechanical ventilation (either within or after 48 hours), ICU length of stay, location after ICU discharge, and hospital mortality.

Among the 50 patients in the UC group whose charts were randomly selected for review, 34 (68%) were weaned, and 1 was discharged on mechanical ventilation. Fourteen of these 34 patients (41%) were successfully weaned using intermittent T-piece trials. Fourteen were weaned using pressure support, four (12%) by both pressure support and T-piece trials (changing mode after failure to progress), and two patients were weaned using intermittent mandatory ventilation. Sixty-five percent of the successfully weaned patients were extubated after their first SBT (either CPAP or T-piece), 15% after their second, and the remainder required three or more SBTs before successful weaning. Mean ± SD pulse oximetric measurement of arterial oxygen saturation at the initiation of the SBT was 97 ± 2.1%. Six patients, including three with an endotracheal tube larger than 7 mm, had their SBT on low levels of pressure support immediately preceding extubation. Four patients underwent a SBT while on vasopressors. For comparison, among the patients in the PW group who were weaned, 54% required only one SBT, 19.5% required two, and the remainder required three or more. Mean oxygen saturation at the initiation of the SBT was 97 ± 2.4%.

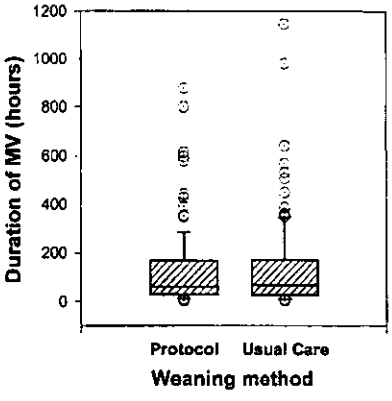

Figure 2. Duration of mechanical ventilation, by treatment group, among patients who discontinued mechanical ventilation before ICU discharge. The *horizontal line* is the median. The *box* denotes 25–75th percentile, and *whiskers* denote 10% and 90% confidence limits. Protocol group, n = 115; traditional group, n = 109; p = 0.61 by Wilcoxon rank sum.

DISCUSSION

We could not document any improvement in clinical outcomes with the use of a nursing/respiratory therapy-driven protocol for discontinuing mechanical ventilation. The protocol we used was similar to that previously shown to speed weaning in medical and coronary ICU patients (3). Our protocol was more aggressive in a few respects. First, patients could be advanced to a f/VT determination even if they were still on vasopressors. Second, we did not require a physician order to begin a SBT. Finally, we required only 1 hour of spontaneous breathing before discontinuing mechanical ventilation, based on a report that as little as 30 minutes of a SBT may be sufficient to identify patients likely to breathe unassisted (20).

A protocol will be ineffective if it is not followed. Poor compliance with study procedures has been noted in a previous investigation in which a protocol shown to be effective in shortening mechanical ventilation duration in one setting was not effective elsewhere (14). In this investigation, we documented rates of

TABLE 3. SECONDARY OUTCOMES BY GROUP

Outcome	Group		p Value
	PW	UC	
Duration of SBT, hr, median (IQR)	3.0 (1.3–5.6)	1.6 (0–3.9)	< 0.01
Reinstitution of mechanical ventilation, n (%)			
≤ 48 hr	9 (5.8)	10 (6.9)	0.71
> 48 hr	7 (4.6)	3 (2.1)	0.23
ICU length of stay, hr, median (IQR)	115 (67–259)	146 (81–291)	0.10
Location after ICU discharge, n (%)			
In-patient floor	84 (54.6)	80 (55.2)	0.32
Died	39 (25.3)	41 (28.3)	
Intermediate care unit	15 (9.7)	9 (6.2)	
Home	4 (2.6)	8 (5.5)	
Other ICU	5 (3.4)	2 (1.4)	
Other hospital	3 (2.0)	2 (1.4)	
Chronic ventilator unit	3 (2.0)	0 (0.0)	
Other	1 (0.6)	3 (2.1)	
Hospital deaths, n (%)	56 (36.4)	48 (33.1)	0.55

Definition of abbreviations: ICU = intensive care unit; IQR = interquartile range; PW = protocol-directed discontinuation of mechanical ventilation; SBT = spontaneous breathing trial; UC = traditional physician-directed discontinuation of mechanical ventilation.

compliance with the study procedures in the intervention group, which compare favorably with similar studies. In other studies of weaning protocols, compliance with the screening step ranged from 60 (5) to 95% (3). The compliance with the SBT step in eligible patients also varied widely in other studies from 10–81% (14). In this study, we cannot distinguish weaning steps that were omitted because of simple oversight from steps that were omitted because of clinical judgment (e.g., a patient undergoing a procedure). Moreover, in this study, only 10 (3.3%) enrolled patients were withdrawn by treating physicians. Thus, we do not believe that inadequate compliance to study procedures explains the difference between this study and others addressing the same question.

A protocol may not be needed if it merely codifies a set of behaviors that are already in use. It is possible that the house staff and attendings had already incorporated some strategies that have been shown to speed weaning into their regular practice. Although we did not prospectively record physicians' approaches to discontinuing mechanical ventilation in the UC group, our chart review found that patients in UC were weaned by a variety of methods. Therefore, it is unlikely that the use of once-daily T-piece trials was an essential element of expeditious weaning. We also did not find evidence of a notably aggressive style of weaning in the UC group, as few of these patients were weaned while on vasopressors or were extubated directly from low levels of pressure support, and arterial oxygen saturation was well above minimum acceptable levels at the beginning of SBTs.

What factors then may have allowed physicians to function as well as the protocol? We believe one simple but important factor is the amount of attention that can be provided to assess patients' readiness to breathe unassisted. Unstable, critically ill patients demand physician attention, and thus, it is nearly unavoidable that stable patients (e.g., those needing only mechanical ventilation discontinuation) fall to a lower priority. When physician availability is a limiting factor in weaning, a protocol can fill that gap. However, when more physicians are available, there may be little chance for a weaning protocol to improve care. To help us further explore this possibility, the authors of previous clinical trials that evaluated protocols for weaning generously provided information to allow us to compare physician staffing levels across studies. We considered the number of ICU beds, the number of physicians assigned to the ICU, and the average number of hours they were present in the ICU each day (during the day and overnight) to calculate the number of physician-hours per bed per day in each of the studies. Compared with approximately 9.5 physician-hours/bed/day in this study, physician staffing was considerably less in the three previous randomized clinical trials: 3.5 physician-hours/bed/day (personal communication, E.W. Ely, M.D., M.P.H.) (3), 4.0 physician-hours/bed/day (personal communication, M.H. Kollef, M.D.) (5), and 4.7 physician-hours/bed/day (personal communication, G. Marelich, M.D.) (6). Although the optimal level of physician staffing for critically ill patients is not known, we speculate that the twofold to threefold increased levels of physician staffing in our ICU may have allowed more timely discontinuation of mechanical ventilation in patients ready to breathe unassisted, rendering the protocol unnecessary. This explanation is supported by results of recent studies reporting an inverse relationship between workload and patient outcomes in ICU and other healthcare settings (16, 21–23).

Another potential explanation is our use of a printed rounding template that covers each of the physiologic systems and then becomes the house staff progress note (reprinted in the online supplement). Similar templates were not in use during other randomized, controlled trials of weaning protocols (3, 5, 6) (personal communications, E. Haponik, M.D.; M.H. Kollef, M.D.; and S. Murin, M.D.). Although the template does not specifically address weaning, it may have helped prompt the team to address ventilator issues each day. In support of this explanation, the use of a simple checklist on rounds was recently shown to reduce the length of stay in a surgical/oncologic ICU (17).

Our findings might suggest that protocol-directed weaning would reduce needs for costly physician staff time. Protocols generally address focused and specific problems that are common, formulaic, and relatively straightforward. However, adequate numbers of skilled and sentient staff can promptly recognize and treat multiple subtle or complicated issues that may not be suitable for management by protocol. Adequate nursing staff, like protocols, have been shown to improve ICU outcomes, including discontinuation of mechanical ventilation and mortality (16, 21–24). In this study, the observed hospital mortality rates of 36.4% and 33.1% in PW and UC groups compare favorably with the mortality rates predicted by their Simplified Acute

Physiology Score II severity of illness score on ICU admission (50.5%, p = 0.02, and 48.8%, p = 0.008, respectively; p values for observed vs. predicted in each group). Intensivist-led or closed ICUs have been shown to improve ICU mortality (15, 16). For these reasons, we do not believe that ICU protocols can substitute for qualified physician and nursing staff. Greater staffing levels are expensive. However, costs of insufficient staff, although hidden to hospital administrators, may be greater.

Our study has several potential limitations. As in other similar unblinded studies (3, 5, 6, 9), it is possible that some physicians, nurses, or respiratory therapists may have changed their UC ventilator management practice because they knew the study was underway (Hawthorne effect). If they reverted to less salutary practice after the trial period ended, the effectiveness of the protocol during a more typical period might have been obscured.

Our allocation process by even or odd medical record number was only quasirandomized and therefore potentially subject to selection bias. Medical record numbers are assigned administratively by a computer in order of a patient's first contact with our medical system, without regard to age, sex, race, diagnoses, ICU admission, etc. This system allowed patients to be assigned to a group immediately on admission without intervention by the investigators and contributed to there being few patients who were inadvertently overlooked (just 4 of 749 admissions, 0.5%). The small number of subjects (six) who were excluded by their treating physicians also suggests that there was no bias to the treatment assignments.

There was a clinically unimportant but significantly longer interval between the initiation of the final SBT and extubation in the patients weaned by protocol. We believe we understand why this occurred. In PW patients who successfully completed 1 hour of a SBT, nurses were often reluctant to interrupt attending physician rounds (generally from 8–11 A.M.) for an order to discontinue mechanical ventilation. Physicians on rounds, if interrupted, were also likely to postpone a decision if that patient had not yet been reviewed by the team. In contrast, physicians were likely to review and promptly act on the results of a SBT that they had initiated in patients assigned to UC.

Finally, our data on the UC group are limited by the retrospective chart review. It is difficult to infer the factors motivating physicians in that group, and the influence of staffing levels, the rounding template, or other factors remains speculative and subject to prospective confirmation.

Conclusions

In summary, in contrast to previous reports, weaning by nursing and respiratory therapy according to a protocol did not reduce duration of mechanical ventilation, length of stay, or mortality compared with weaning by physicians. We speculate that this lack of benefit may have been due to the high levels of physician staffing in our intensivist-run closed ICU or the use of a template on rounds to promote daily discussion of mechanical ventilation on each patient. Protocols, which are laborious to design and implement, do not necessarily improve patient care and should be tested in the setting in which they are to be applied. The most cost-effective ICU physician staffing level is unknown and will vary among ICUs. However, intensivists inarguably should be attentive to weaning. This attention may be promoted by a weaning protocol, structured rounds, additional staffing, or other tools to ensure that the ability to breathe is recognized promptly.

Conflict of Interest Statement: J.A.K. has no declared conflict of interest; D.M. has no declared conflict of interest; C.R. has no declared conflict of interest; C.S.R. has no declared conflict of interest; H.E.F. has no declared conflict of interest.

Acknowledgment: The authors are indebted to the respiratory therapists and nurses of the Johns Hopkins Medical Intensive Care Unit. Without their enthusiasm, diligence, and skill, this study could never have been completed. They also want to thank Dr. Edward Haponik, M.D., for his helpful discussion and suggestions.

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3.8

Knowledge Based Weaning: Protocolized Care in the Weaning Process

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Improving Intensive Care Unit (ICU) outcomes by reducing ventilator associated complications and ventilator days may warrant re-engineering the weaning process.[1] Alternative methods which assist clinicians in organizing and implementing accurate weaning processes may shorten the duration of ventilator dependence and positively impact ICU outcomes.[2] Knowledge based weaning (KBW) provides an alternative to the traditional weaning process.

A major challenge in the ICU is determining whether a patient is capable of weaning from the ventilator. Weaning patients from mechanical ventilation is initiated by the bedside clinician, not the ventilator.[3] Reductions in the level of ventilator support are typically performed once or twice a day during routine ventilator checks or at designated times, generally during daytime hours. The weaning process characteristically begins when the clinician believes the patient is able to tolerate less support, and is present to make appropriate changes in ventilator settings. Decisions to proceed with the weaning process by the respiratory therapist or physician are commonly intermittent and unstructured. Optimal ventilator settings during weaning are those which provide the lowest level of support and prevent excessive work of breathing and fatigue. Once committed to the weaning process, optimal ventilator settings should be maintained throughout. Progressive reduction of ventilator support requires frequent reassessment to determine whether to maintain, reduce or escalate ventilator support. Respiratory decompensation may not be recognized until significant fatigue has developed. Current methods of weaning rely on a reactive approach to detect inappropriate ventilator weaning. Excessive weaning may surpass the patient's ability to transition to less support, paradoxically prolonging ventilator dependence. Conversely, data suggests many patients are ventilated longer than necessary. Prospective, controlled studies have shown that greater than 70% of patients who tolerate a spontaneous breathing trial could be extubated successfully.[4,5,6] These studies advocate a spontaneous breathing trial to identify patients capable of being liberated from mechanical ventilation. In addition, studies reviewing self-extubation have documented a significant percentage of self extubated patients do not require reintubation. These studies suggest that care providers may not always recognize patients' readiness to be weaned and extubated.[7,8]

Complications from mechanical ventilation are associated with significant mortality, morbidity, increased ICU length of stay and ICU cost.[9] Ventilator associated lung injury and pneumonia are significant morbidities directly related to duration of ventilator dependence.[10] The need for continuous quality improvement has caused many ICU clinicians to focus on reducing ventilator days and complications from mechanical ventilation. In 1994, Esteban suggested that weaning from the ventilator accounts for up to 42% of the time a patient is mechanically ventilated.[11]

Multidisciplinary protocols can improve the weaning process through the implementation of a consistent, team approach.[12] Protocol based weaning defines and organizes a process for ventilator adjustments, expected outcomes, patient monitoring and patient care during weaning. Several studies have shown that implementation of protocols to aid the weaning process results in a significant reduction in ventilator days and cost.[2] Furthermore, reductions in ventilator days directly impacts ventilator associated complications. Successful protocol based weaning results from a coordinated approach using a multidisciplinary team rather than the mode of ventilator weaning. The multidisciplinary team approach to designing and implementing weaning protocols provides the opportunity to incorporate knowledge from several disciplines on how the weaning process affects patients. In addition, the multidisciplinary approach facilitates the coordination of care plans during the weaning process.[13] The multidisciplinary team should include nutritionists, pharmacists, physical and occupational therapists in addition to physicians, respiratory therapists and nurses. A diversity of clinical staff provides a well-rounded assessment of the patient, plan of care and

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expected outcomes. Effective protocols must balance adequate information to deal with the complexity of weaning and limit data overload for the clinician. If a protocol becomes too difficult to navigate, the protocol may not be utilized appropriately. Protocols with excessive detail may decrease their effectiveness, increase error rates and even limit successful implementation. Alternatively, if a protocol does not have enough detail, application may be limited to a narrow spectrum of patients, proving ineffective for clinical variability inherent in critical care patients.[14]

KBW computer software incorporates clinical logic and rules coupled to a knowledge base in order to automate the weaning process.[15] Automated weaning may provide several advantages over traditional methods of weaning. KBW facilitates data acquisition and monitoring, continually supplying information to the knowledge base. The knowledge base maintains current medical data and practice patterns from a multidisciplinary team to define and organize weaning.[16,17,18] The knowledge base engages the reasoning engine to provide rules for the weaning process. KBW provides the basis for organized, consistent and continuous weaning to reduce clinical variability. Furthermore, KBW allows the complexity of the weaning process to be transparent to the end user, improving the user interface. Improving the user interface has the potential to improve compliance, prevent process confusion and errors while limiting data overload.

Improved monitoring and trending coupled with a reasoning engine can guide therapy and allow weaning to progress over the entire 24 hour period. In addition, continuous monitoring provides trends of "smart alerts" which may signal impending weaning failure, providing a proactive weaning system. Reengineering the weaning process provides the potential to improve outcome while decreasing cost. KBW will provide a foundation for weaning in the 21st century.

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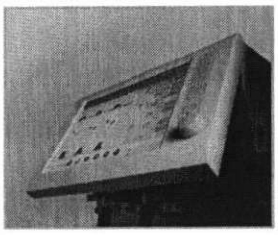
3.9

SMARTCARE™ WEANING SOFTWARE Found on DRAEGER'S EvitaXL VENTILATOR

Paul Mathews PhD, RRT & Bethene Gregg PhD, RRT

Decisions to proceed with weaning by the respiratory therapist or physician are commonly intermittent and unstructured. Optimal weaning settings are those which provide the lowest level of support and prevent excessive work of breathing and fatigue. We also know that once committed to the weaning process, optimal settings, adjusted as needed, should be *maintained* throughout. Progressive reduction of ventilator support, however, requires frequent reassessment to determine whether to maintain, reduce or escalate ventilator support. Current methods of weaning, unfortunately, often rely on a ***reactive*** approach to detect inappropriate ventilator settings, an approach that can, paradoxically, prolong ventilator dependence instead of decrease it.



The trend, in modern respiratory therapy is to increasingly move towards assisted forms of mechanical ventilation, for, as the saying goes, "weaning begins with intubation." It's a training process for respiratory muscles, much like athletes undergo to improve performance, and, in consideration of the current pathophysiologic understanding of acute lung injury, spontaneous breathing modes should be used as much as possible. Constantly adjusting ventilator settings according to the changing demands and needs of the patient, however, is a major problem in the daily routine of almost every ICU or "weaning unit".

Enter SmartCare™PS, Dräger Medical's weaning program integrated into their EvitaXL ventilator. SmartCare was developed as a knowledge-based weaning system resulting from a protocol developed by Brochard and coworkers in Europe. Their approach included a special innovation of a derived pressure support mode that let's the ventilator react to the patient's demand for an adjusted ventilatory support classified by SmartCare every two to five minutes. SmartCare is not only a computer system, then, but, a bedside-tested clinical protocol for weaning that aims for comfortable recovery from respiratory failure and liberation from the ventilator.

As we know, traditional weaning technique has in the last decade or so, been based on periodical clinical judgments of the patient's respiratory status, reduction of sedoanalgesics, early use of pressure support ventilation, CPAP and ventilator independence, including spontaneous breathing trials with T-piece. The main problem, however, was the need for considerable staff to monitor all this in a frequently understaffed work environment.

SmartCare's computer software, which encompasses patient weight ranges of 15kg – 200kg, incorporates clinical logic and rules coupled to a knowledge base in order to "automate" the weaning process. Automated weaning may provide several advantages over traditional methods. First, the software facilitates data acquisition and monitoring, continually supplying information to the knowledge base. The knowledge base maintains current medical data and practice patterns to define and organize weaning. The knowledge base then engages the reasoning engine to provide rules for the weaning process and the software provides the basis for *organized*, more *consistent* and *continuous* weaning to reduce clinical variability. Furthermore, the software allows the complexity of the weaning process to be transparent to the end user, improving the user interface which can improve compliance, prevent process confusion and prevent errors.

Improved monitoring and trending, coupled with a reasoning engine, can guide therapy and allow weaning to progress over an entire 24 hour period. In addition, continuous monitoring provides trends of "smart alerts" which may signal impending weaning failure, providing a ***proactive*** weaning system. This has the potential to improve outcome while decreasing cost, perhaps a new foundation for weaning in the 21st century.

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So, how does it really work?

SmartCare Software 1.1 for the Dräger EvitaXL 6.0 (or higher), automatically adjusts pressure support levels to maintain spontaneous breathing frequency, tidal volume and end-tidal CO2 parameters within a predetermined range. This feature, found only on the EvitaXL, has been in successful clinical use for approximately one year now and Drager has numerous studies showing how their software can significantly reduce weaning time (www.draegermedical.com for more information).

The software presents three sets of values based on actual body weight of the patient. These are, "15 to 35 kg", "36 to 55 kg", and "over 55 kg". Each body weight range has different criteria for acceptable tidal volume and frequency. Based on the patient's initial frequency, tidal volume and etCO2, SmartCare assigns the

continued on page 69

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patient's ventilation to one of eight categories: normal ventilation, insufficient ventilation, hypoventilation, central hypoventilation, tachypnea, severe tachypnea, hyperventilation, or a category called "unexplained hyperventilation". For example, normal ventilation for patients weighing over 55 kg is defined as a spontaneous frequency between 15 and 30 breaths/minute, a tidal volume over 300 ml, and an etCO2 below 55 mm Hg. "Insufficient ventilation" is classified as an acceptable frequency, but with a tidal volume that is too low or where an etCO2 is too high. Hypoventilation on the other hand, is considered to be an acceptable tidal volume but with a frequency that is too low and an etCO2 that is too high. The remaining types of ventilation are similarly delineated. The software presents a screen to the user which allows the user to select "Neurological Disorder", "COPD" or both under "Medical History". Choosing "Yes" for neurological disorder for instance, sets the high frequency limit to 34 breaths/minute for body weights of 36 kg and over. Selecting the "COPD" setting, allows the high etCO2 limit to rise to 65 mm Hg.

Ventilation other than normal will initiate an increase or decrease in pressure support by 2-4 cm's H2O, within a specified period of time depending on which parameter limit was violated. If a patient has an endotracheal tube and a HME humidifier, the target pressure support for ventilator discontinuance is 12 cm's H2O. The pressure support goal for a patient with a tracheostomy tube and wet humidifier, for instance, is five cm's H2O. When the target pressure has been obtained, SmartCare conducts a spontaneous breathing test, and if successful, displays a message ("SC – CONSIDER SEPARATION" to the therapist indicating that the patient may be considered for separation from the ventilator.

SmartCare checks the patient's RR, Vt and etCO2 every 10 seconds. It will analyze ventilation every two minutes if there was no PS change or every 5 minutes if there was a PS change; certainly more often than any therapist could. The objective of SmartCare of course, is to obtain a target level of pressure support that is tolerated well and which eventually indicates the patient's readiness to be discontinued from the ventilator. We were able to reproduce the various categories of ventilation in our laboratory using a Duel Adult Test Lung made by Michigan Instruments, Inc.. We connected the EvitaXL capnograph to the drive section of the test lung as well, and bled in a low flow rate of a 10 % CO2 gas mixture to control the etCO2 values. Bleeding CO2 into the "patient" test lung produced a "Flow measurement out of range" message and SmartCare would interrupt, as it was designed to do. (External flow compensation cannot be used with SmartCare which, unfortunately, means delivery of externally driven aerosol therapy is not allowed during SmartCare.) The use of the Evita *internal* nebulizer, however, ***is*** possible during a SmartCare session allowing delivery of aerosol therapy via this route. As each of the types of ventilation were simulated and a parameter threshold was breeched, SmartCare increased (or decreased) the level of pressure support; again, as it was designed to do. We also *purposefully* interrupted SmartCare numerous times so as to test the software's response. When interrupted, the SmartCare symbol (with a diagonal line through it) appeared on the screen and the current level of pressure support was maintained until the offending condition had been corrected – a good thing to see. When alarm limits are activated, SmartCare may be re-activated by touching "Alarm Reset". SmartCare can also be interrupted by design, say, for overnight resting periods, by activating the "Night Rest" mode; another nice feature.

SmartCare is interrupted with sensor alarms or airway pressure alarms and aborted altogether with Apnea Ventilation. It will not be available at all if: 1) the patient's body weight isn't entered in the SmartCare section, 2) external flow compensation is active, or 3) the CO2 sensor is not functioning.

SmartCare is designed to be just as flexible as the EvitaXL ventilator itself and there is a separate guideline for patients with body weight between 15 and 35 kg. For all other patients Draeger's ATC™ may be used during the weaning session. In this way SmartCare not only adapts to the patient population, but also allows one to incorporate *their* therapy strategy, whether it is with, or without, ATC.

As a result of our review, SmartCare seems to meet the requirements for a knowledge-based weaning system, even in long-term ventilated patients. SmartCare should shorten weaning time and should help busy therapists to more closely monitor and adjust their patient's ventilatory support. Of course it does not forgo the need for attention by a knowledgeable respiratory therapist, however. Still, with SmartCare, Draeger takes the first step to "smarter" medical equipment. Adding intelligence to their mechanical ventilator by integrating "protocolized" care based on recognized medical expertise is certainly a leap forward. Another advantage of this system is its easing of the need for more and more staff. Even if the staff of an ICU makes every endeavour possible to wean a patient from the ventilator, the therapist can not be at the patient's bedside every minute of the day as SmartCare can.

Maintaining high quality patient care while reducing the clinical workload, increasing patient comfort during ICU treatment, reducing the time spent on a ventilator and shortening the patient's stay in the ICU and the hospital, are most definitely "smart" goals. SmartCare does seem to contribute to those goals thus, we recommend that you take a good look at Dreager's EvitaXL and its SmartCare weaning system, the next time you're in the market for mechanical ventilators.

The company can be reached at 800-437-2437. They also have an extensive website located at ww.draegermedical.com.

(b)(4) Trade Secret Process - Product Specs

[redacted]

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Performance and Testing Data (Section 10)

(b)(4) Trade Secret Process - Testing

[redacted]

213

(b)(4) Trade Secret Process - Testing

[redacted]

214

[1] SmartCare / PS was initially used under the project name Automedon-PS

(b)(4) Trade Secret Process - Product Specs

[redacted]

215

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

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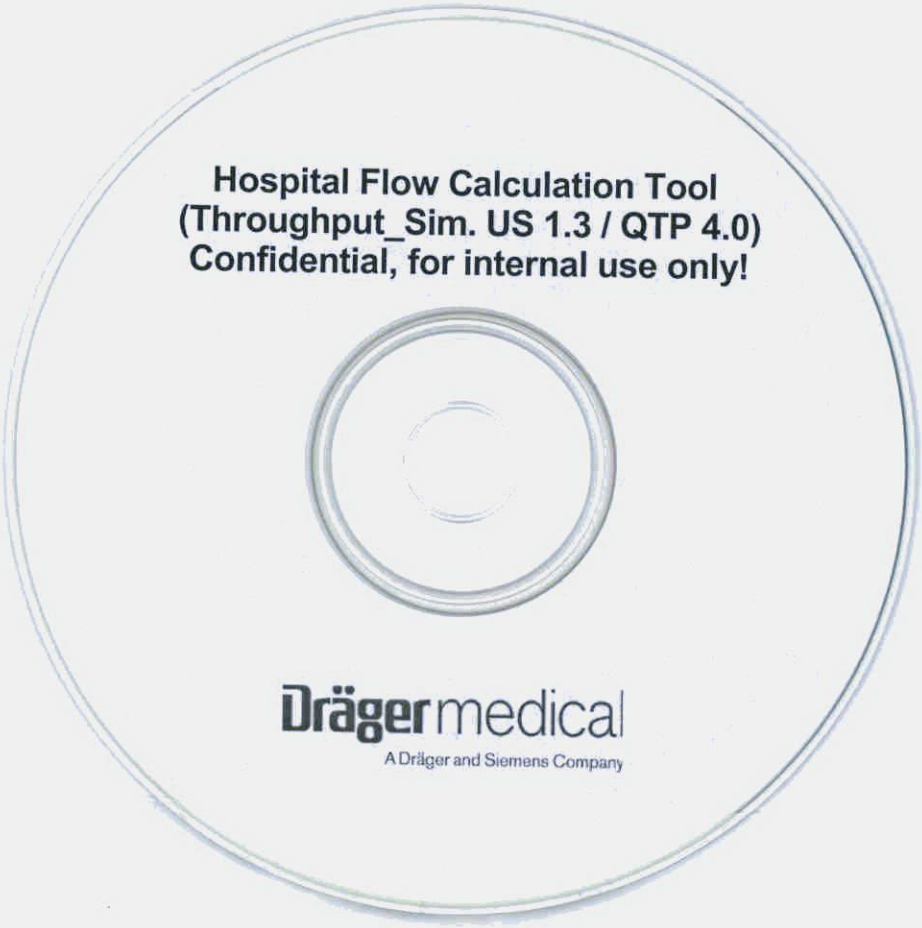
Hospital Flow Calculation Tool
(Throughput_Sim. US 1.3 / QTP 4.0)
Confidential, for internal use only!
Drägermedical
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

January 24, 2008

DRAGER MEDICAL AG & CO. KGAA
C/O DRAGER MEDICAL , INC.
3135 QUARRY ROAD
TELFORD, PA 18969
ATTN: KATHY ANDERSON

510(k) Number: K072412
Product: OPTION SMARTCARE FOR EVITAXL,SMARTCAR E KIT CAPNO

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Drägermedical

A Dräger and Siemens Company

K073412/S2

Dräger Medical AG & Co. KG, Moislinger Allee 53-55, 23542 Lübeck, Germany

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
Attn. Mr. Charles Kerns
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E mail
gustav.paulsen@draeger.com

Special 510(k) Premarket Notification Option SmartCare / PS for the EvitaXL (K072412)
2nd Additional Information

Dear Mr. Kerns,

In response to your request for additional information dated December 31, 2007 for Option SmartCare / PS for the EvitaXL ventilator, please find attached the information requested.

Please find enclosed two (2) paper copies of additional information.

If there is a need to discuss any aspect of this Premarket Notification, please contact either the undersigned at +49 (451) 882-5367, or the assigned United States agent Ms. Kathy Anderson, Dräger Medical System, Inc., at (215) 660-2078.

With best regards,

Gustav Paulsen
Manager Regulatory Affairs

Dr. Karin Lübbers
Senior Manager Regulatory Affairs

Enclosure: Two paper copies submitted,
Attachment: CDRH Submission Cover Sheet

K8

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
1/18/2008		K072412

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Dräger Medical AG & Co. KG	Establishment Registration Number *(if known)* 9611500		
Division Name *(if applicable)* N/A	Phone Number *(including area code)* (+49) 451-882-5367		
Street Address Moislinger Allee 53-55	FAX Number *(including area code)* (+49) 451-882-4351		
City Luebeck	State / Province N/A	ZIP/Postal Code D-23542	Country Germany
Contact Name Dr. Karin Luebbers			
Contact Title Senior Manager, Regulatory Affairs	Contact E-mail Address karin.luebbers@draeger.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name Draeger Medical Systems, Inc.			
Division Name *(if applicable)* N/A	Phone Number *(including area code)* (215) 660-2078		
Street Address 3135 Quarry Rd.	FAX Number *(including area code)* (215) 721-5424		
City Telford	State / Province PA	ZIP/Postal Code 18969	Country U.S.A.
Contact Name Kathy Anderson			
Contact Title Senior Director, Regulatory Affairs	Contact E-mail Address kathy.anderson@draeger.com		

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	CBK	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☐ 510 (k) summary attached
- ☐ 510 (k) statement

rmation on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K051263	1	EvitaXL with Option SmartCare	1	Dräger Medical AG & Co. KG
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device		Model Number
1	Option SmartCare for EvitaXL	1	84 15 941
2	SmartCare kit Capno package	2	84 15 942
3	CO2 sensor CapnoSmart	3	68 71 500
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
CBK	868.5895	☐ Class I ☒ Class II
Classification Panel: Anesthesiology		☐ Class III ☐ Unclassified

Indications *(from labeling)*

please see Section 4 of the 510(k) submission

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number 9611500	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name Dräger Medical AG & Co. KG		Establishment Registration Number 9611500		
Division Name *(if applicable)* N/A		Phone Number *(including area code)* (+49) 451-882-5357		
Street Address Moislinger Allee 53-55		FAX Number *(including area code)* (+49) 451-882-4351		
City Luebeck		State / Province N/A	ZIP/Postal Code D-23542	Country Germany
Contact Name Dr. Karin Luebbers	Contact Title Senior Manager/Regulatory Affairs		Contact E-mail Address karin.luebbers@draeger.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
..eet Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
ntact Name	Contact Title		Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Shipping Order

Date: 21. Januar 2008 14:07:17

Order No.: **0801217325**

Consignee:

Food and Drug Administration
Center for Devices and Radiological
Health, Document Mail Center (HFZ-401)
Attn. Mr. Charles Kerns
9200 Corporate Boulevard
Maryland
US - 20850 Rockville

Consigner:

Name.:	Paulsen, Gustav
	H3
Charged cost center:	4130
Sending cost center:	4130
Company:	DMT
Department:	mt-pq-ra
Phone:	0451/882-2041
Typist:	Paulsen, Gustav

Reference: 2008-01-21 - Documents

Shipping Point:	Dispatch type:	Delivery Date:	Delivery Time:	Incoterms:	No. of consolidated Shipment:
WVZ	Courier	23.01.2008	14:00	CIP	

Comment: Bitte AWB-Nummer und Kurierservice per Fax an 75425 faxen!

Pos.	Quantity	Part No.	Description	Dangerous goods	Value/€
10	1		two binder documents	No	0,00
			Sum:		0,00

Net weight	Gross weight	L x B x H	Box	Packer

Drägermedical
A Dräger and Siemens Company

Dräger Medical AG & Co. KG, Moislinger Allee 53-55, 23542 Lübeck, Germany

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
Attn. Mr. Charles Kerns
9200 Corporate Boulevard
Rockville, Maryland 20850
USA

Date
2008-01-18
Our ref.
mt-pq-ra_smarcare
Phone
+49 (0) 451 882 2041
Fax
+49 (0) 451 882 72041
E mail
gustav.paulsen@draeger.com

PROFORMA INVOICE

Delivery of documents (2 binders) for approval of a medical device.

Delivery free of charge.

Value (for customs purposes only): 25,-€

Sincerely,

Gustav Paulsen
Manager Regulatory Affairs

Enclosure: two paper copies submitted,
Attachment: CDRH Submission Cover Sheet, Medical Device User Fee Cover Sheet

Dräger Medical AG & Co. KG
Moislinger Allee 53-55
D - 23558 Lübeck
Postanschrift: 23542 Lübeck
Telefon +49-18 05-3 72 34 37
Telefax +49-4 51-8 82-37 79
E-mail: business-support@draeger.com
www.draeger.com
UID-Nr.: DE812119413
Steuernummer 22 283 42757

Commerzbank AG, Lübeck
Konto-Nr. 0146795 00
BLZ 230 400 22
IBAN: DE95 2304 0022 0014 6795 00
SWIFT-Code: COBA DE FF 230
Dresdner Bank AG, Lübeck
Konto-Nr. 371 077 400
BLZ 230 800 40
IBAN: DE28 2308 0040 0371 0774 00
SWIFT-code: DRES DE FF 230

Sparkasse zu Lübeck
Konto-Nr. 107 111 7
BLZ 230 501 01
IBAN: DE15 2305 0101 0001 0711 17
SWIFT-Code: HSHN DE H1 SPL

Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRA 4435 HL

Komplementär:
Dräger Medical Verwaltungs AG
Sitz der Gesellschaft: Lübeck
Handelsregister:
Amtsgericht Lübeck HRB 5035
Vorsitzender des Aufsichtsrates:
Dipl.-Kfm. Theo Dräger
Vorstand:
Dr. Volker Pfahlert (Vors.)
Dipl.-Kfm. Roland Jaksch

Drägermedical
A Dräger and Siemens Company

Dräger Medical AG & Co. KG, Moislinger Allee 53-55, 23542 Lübeck, Germany

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
Attn. Mr. Charles Kerns
9200 Corporate Boulevard
Rockville, Maryland 20850
USA

Date
2008-01-18
Our ref.
mt-pq-ra_smarcare
Phone
+49 (0) 451 882 2041
Fax
+49 (0) 451 882 72041
E mail
gustav.paulsen@draeger.com

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Drägermedical
A Dräger and Siemens Company

Dräger Medical AG & Co. KG, Moislinger Allee 53-55, 23542 Lübeck, Germany

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
Attn. Mr. Charles Kerns
9200 Corporate Boulevard
Rockville, Maryland 20850
USA

Date
2008-01-18
Our ref.
mt-pq-ra
Phone
+49 (0) 451 882 2041
Fax
+49 (0) 451 882 4351
E mail
gustav.paulsen@draeger.com

Special 510(k) Premarket Notification Option SmartCare / PS for the EvitaXL (K072412)
2nd Additional Information

Dear Mr. Kerns,

In response to your request for additional information dated December 31, 2007 for Option SmartCare / PS for the EvitaXL ventilator, please find attached the information requested.

Please find enclosed two (2) paper copies of additional information.

If there is a need to discuss any aspect of this Premarket Notification, please contact either the undersigned at +49 (451) 882-5367, or the assigned United States agent Ms. Kathy Anderson, Dräger Medical System, Inc., at (215) 660-2078.

With best regards,

Gustav Paulsen
Manager Regulatory Affairs

Dr. Karin Lübbers
Senior Manager Regulatory Affairs

Enclosure: Two paper copies submitted,
Attachment: CDRH Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
1/18/2008		K072412

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion.	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name Dräger Medical AG & Co. KG	Establishment Registration Number *(if known)* 9611500		
Division Name *(if applicable)* 'A	Phone Number *(including area code)* (+49) 451-882-5367		
Street Address Moislinger Allee 53-55	FAX Number *(including area code)* (+49) 451-882-4351		
City Luebeck	State / Province N/A	ZIP/Postal Code D-23542	Country Germany
Contact Name Dr. Karin Luebbers			
Contact Title Senior Manager, Regulatory Affairs	Contact E-mail Address karin.luebbers@draeger.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name Draeger Medical Systems, Inc.			
Division Name *(if applicable)* N/A	Phone Number *(including area code)* (215) 660-2078		
Street Address 3135 Quarry Rd.	FAX Number *(including area code)* (215) 721-5424		
City Telford	State / Province PA	ZIP/Postal Code 18969	Country U.S.A.
Contact Name Kathy Anderson			
Contact Title Senior Director, Regulatory Affairs	Contact E-mail Address kathy.anderson@draeger.com		

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	CBK	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K051263	1	EvitaXL with Option SmartCare	1	Dräger Medical AG & Co. KG
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device		Model Number
1	Option SmartCare for EvitaXL	1	84 15 941
2	SmartCare kit Capno package	2	84 15 942
3	CO2 sensor CapnoSmart	3	68 71 500
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code
CBK

C.F.R. Section *(if applicable)*
868.5895

Device Class
☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Classification Panel
Anesthesiology

Indications *(from labeling)*
please see Section 4 of the 510(k) submission

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number 9611500	☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler		
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Street Address Moislinger Allee 53-55		FAX Number *(including area code)* (+49) 451-882-4351		
City Luebeck		State / Province N/A	ZIP/Postal Code D-23542	Country Germany
Contact Name Dr. Karin Luebbers	Contact Title Senior Manager/ Regulatory Affairs		Contact E-mail Address karin.luebbers@draeger.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
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City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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CDRH (HFZ-342)
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Rockville, MD 20850

..n agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

2nd Additional Information

for the

Option SmartCare / PS for the EvitaXL ventilator

510(k) Premarket Notification (K072412)
Requested on December 31, 2007

001

(b)(4) Trade Secret Process - Product Specs

[redacted]

002

(b)(4) Trade Secret Process - Product Specs

[redacted]

003

Paulsen, Gustav

Subject: RE: Additional Information - K072412

From: Kerns, Charles [mailto:charles.kerns@fda.hhs.gov]
Sent: Monday, December 31, 2007 1:10 PM
To: Anderson, Kathy
Subject: Additional Information - K072412

Dear Ms. Anderson:

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Thank you,

Charles M. Kerns, RN, BSN, MS
CDR USPHS
CDRH/ODE/DAGID/ARDB
HFZ-480, Room 240H
9200 Corporate Blvd
Rockville, MD 20850
240-276-3775
charles.kerns@fda.hhs.gov

(b)(4) Trade Secret Process - Product Specs

[redacted]

006

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401
9200 Corporate Blvd.
Rockville, Maryland 20850

January 02, 2008

DRAGER MEDICAL AG & CO. KGAA
C/O DRAGER MEDICAL , INC.
3135 QUARRY ROAD
TELFORD, PA 18969
ATTN: KATHY ANDERSON

510(k) Number: K072412
Product: OPTION SMARTCARE FOR EVITAXL,SMARTCAR E KIT CAPNO

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

(b)(4) Trade Secret Process - Product Specs

[redacted]

009

Performance and Testing Data (Section 7)

(b)(4) Trade Secret Process - Testing

[redacted]

010

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

[redacted]

013

(b)(4) Trade Secret Process - Product Specs

[redacted]

014

Proposed Device Labeling (revised Section 6)

The device labeling of the EvitaXL and the SmartCare Option in terms of instructions for use and device label (adhesives) is not changed. Thus the material is not included in this submission.

The promotional material included in the first SmartCare submission K#051263 remains in use unchanged and is not included in this submission.

The changes covered by this submission refer only to the promotional material appended to this section. It comprises customer presentations, a print advertisement and an Excel spreadsheet called 'Hospital Flow Calculation Tool'.

Dräger Medical intends to create more promotional material based on the claims stated in this submission.

Summary of Claims

The claims made in the promotional material are summarized as follows:

Medical results:

(b)(4) Trade Secret Process - Product Specs

[redacted]

Time reduction:

(b)(4) Trade Secret Process - Product Specs

[redacted]

Cost reduction:

(b)(4) Trade Secret Process - Product Specs

[redacted]

The concrete presentation of the claims is shown in the appended slides

015

List of Appendices

Appendix 6.1:	Excerpt form Presentation "Impact"
Appendix 6.2:	Excerpt form Presentation "Integrated CareArea™ Solutions for Critical Care"
Appendix 6.3:	Excerpt form Presentation "Impact Solutions for Critical Care Ventilation"
	NOTE: The complete presentations listed under 8.1 - 8.3 cover a wide range of Dräger products. The excerpts included here comprise the SmartCare section of these presentations.
Appendix 6.4:	"Impact" Print Ad
Appendix 6.5:	Presentation: Hospital Flow Calculation Tool (including screen shots)
Appendix 6.6:	Paper: "The Hospital Flow Diagnostic" Description for Excel based Calculation Tool
Appendix 6.7:	CD Rom with Hospital Flow Calculation Tool Contents: • Throughput_Simulation US 1.3 .xls (MS Excel Spreadsheet) • qtp.exe (QTP 4.0, required Excel PlugIn)

Hospital Flow Calculation Tool

The calculation tool uses queuing theory to model patient throughput through a hospital or a single unit based upon admission requests, available beds and length of stay on the ICU.

The tool has neither diagnostic nor therapeutic inputs or outputs.

As potential ICU patients cannot wait for treatment, the allowed queue is zero. The simulation calculates the probability of the ICU being full and therefore the probability that patients that cannot be admitted due to full occupancy of the ICU have to be diverted to other hospitals.

Input parameters for the simulation are:

(b)(4) Trade Secret Process - Product Specs

[redacted]

The actual hospital data are modified allowing for the outcome effects of e.g. SmartCare/PS. The reduced length of stay results in an increased throughput for the ICU. This is shown by the main output parameters of the simulation:

(b)(4) Trade Secret Process - Product Specs

[redacted]

016

These data are transferred into a business case calculation considering the coverage of fix costs of a day at the ICU and the revenues of additionally treated patients. The impact on the financial result of the hospital is shown as the final result of the calculation.

NOTE:

For reviewing the tool please refer to the appended CD ROM. Install QTP (a package of Excel formulas for modeling queues) first. Open 'Throughput_Simulation US 1.3 .xls'

NOTE:

Changes made to the promotional material due to FDA's deficiencies correction are labeled as follows: text portions that were removed are crossed out, their new substitutes are underlined.

017

(b)(4) Trade Secret Process - Draft

[redacted]

018

(b)(4) Trade Secret Process - Draft

[redacted]

019

(b)(4) Trade Secret Process - Draft

[redacted]

020

(b)(4) Trade Secret Process - Draft

[redacted]

021

(b)(4) Trade Secret Process - Draft

[redacted]

022

(b)(4) Trade Secret Process - Draft

[redacted]

023

(b)(4) Trade Secret Process - Draft

[redacted]

024

(b)(4) Trade Secret Process - Draft

[redacted]

025

(b)(4) Trade Secret Process - Draft

[redacted]

026

(b)(4) Trade Secret Process - Draft

[redacted]

027

(b)(4) Trade Secret Process - Draft

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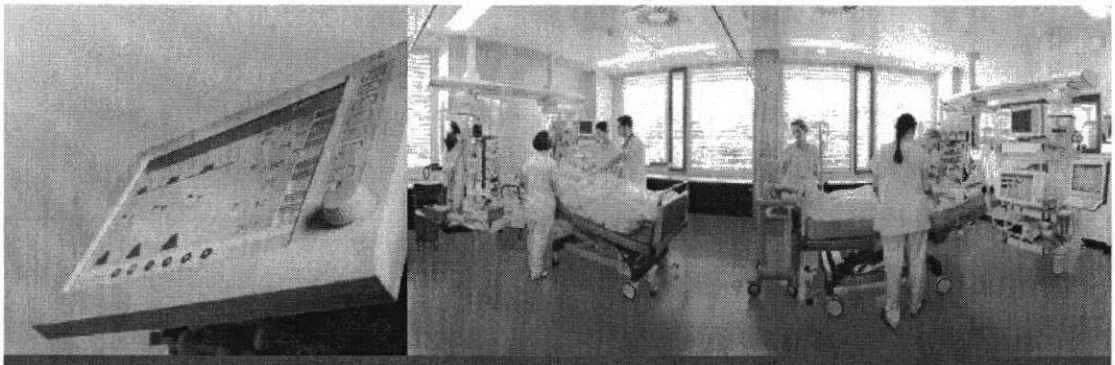
Appendix 6.4: "Impact" Print Ad

Dräger

What's one way to dramatically impact Critical Care?



Reduce overall ventilation time by up to **33%***

with Dräger Medical's SmartCare™ automated weaning. It's not only possible... it's documented. Think of what that can mean to your patients... your productivity... and your bottom line. Yet it's just one aspect of our integrated CareArea™ Solutions for Critical Care... and the entire care process. To discover how all of our innovative solutions can impact your care process, visit www.draeger.com.

*E. Lellouche et al., Intensive Care Medicine 2004, Vol. 30, Supplement 1, 254-P69.
Am J Respir Crit Care Med Vol 174. pp 894-900, 2006

Results are based on a European Multicenter Randomized Trial with 144 patients demonstrating improved respiratory conditions, with stable hemodynamic and neurologic status, and no ARDS prior to initiating weaning.

1907
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100 Years of Innovation in Ventilation.
Dräger. Technology for Life®

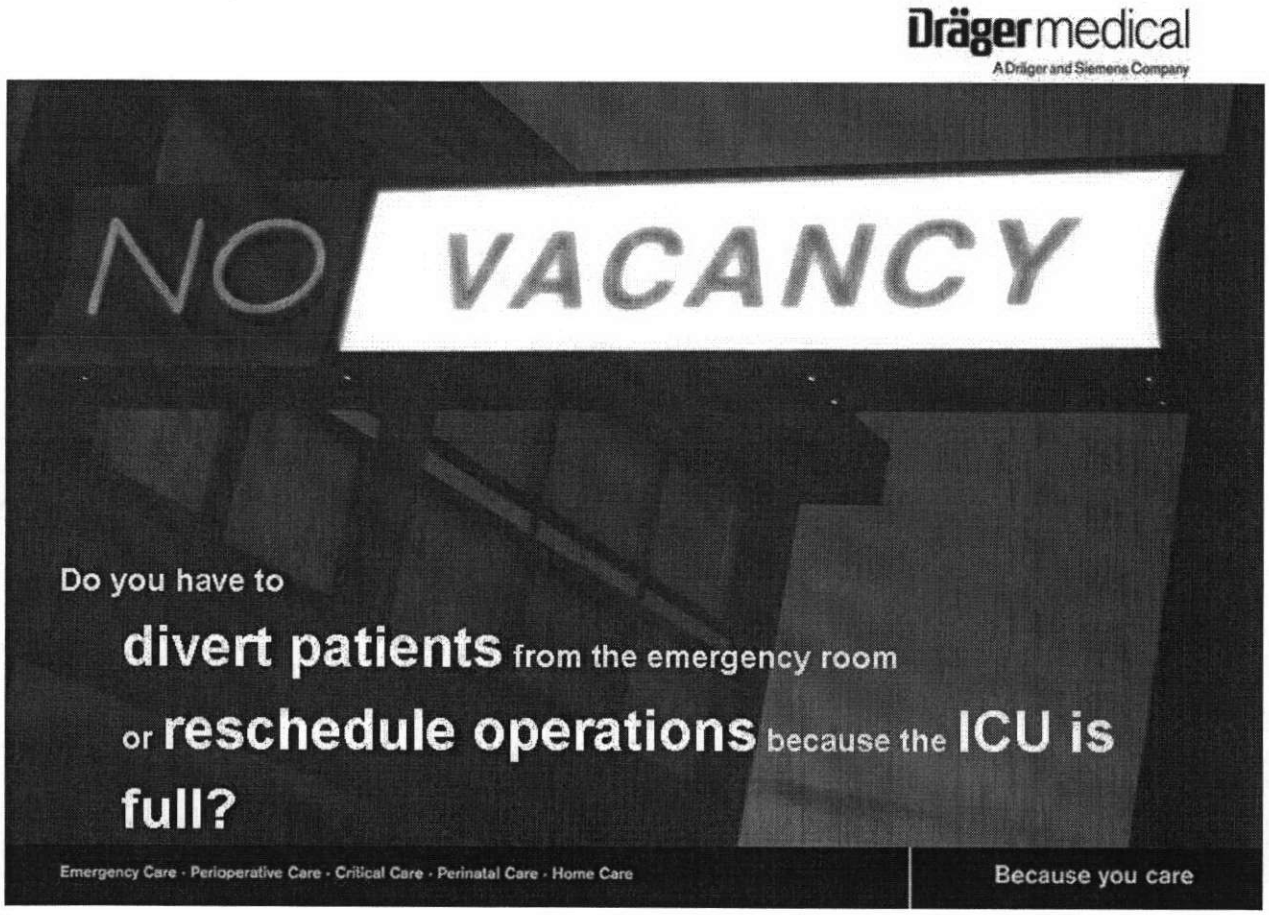
Dräger Medical: Emergency Care > Perioperative Care > Critical Care > Perinatal Care > Home Care

035

Appendix 6.5: Hospital Throughput Calculation Tool

The presentation contained in this appendix gives an overview on the calculation of ICU throughput with the Excel spreadsheet.

Pages that contain screenshots from the spreadsheet are marked with ***)XLS**.



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