7. REPLACEMENT OF CARDIAC MONITORS / DEFIBRILLATORS

COMMITTEE RECOMMENDATIONS AS AMENDED

1. **That Council approve the funding to the Base Hospital Program of Ottawa-Carleton for the immediate purchase of 35 Zoll Medical M Series Monitor / Defibrillators Multi-Pro Plus Model, and training on the new equipment for all paramedics currently working in Ottawa-Carleton, at a total cost of $930,312 (after trade-in). The Ministry of Health and Long-Term Care has agreed to fund $232,631 or 25% leaving the Region with the remaining 75% portion at a cost of $697,681.**

2. **WHEREAS "Early Defibrillation" is the key link in the Chain of Survival for sudden cardiac arrest victims; and**

   WHEREAS Ottawa-Carleton has Advanced Life Support Paramedics; and

   WHEREAS the existing defibrillators are inadequate as a diagnostic and reporting tool for Advanced Life Support Paramedics; and

   WHEREAS the existing defibrillators have passed their serviceable lifespan and are failing;

   THEREFORE BE IT RESOLVED that Council direct staff to seek approval from the Transition Board to allow for the immediate replacement of this equipment.

DOCUMENTATION

1. Medical Officer of Health's report dated 18 April 00 is immediately attached.

2. Extract of Draft Corporate Services and Economic Development Committee Minute, 18Apr 00, will be distributed prior to Council and will include a record of the vote.

REGION OF OTTAWA-CARLETON REPORT
RÉGION D'OTTAWA-CARLETON RAPPORT

Our File/N/Réf.
Your File/V/Réf.

DATE 18 April 2000

TO/DEST. Co-ordinator,
Corporate Services and Economic Development Committee

FROM/EXP. Medical Officer of Health

SUBJECT/OBJET **REPLACEMENT OF CARDIAC MONITORS / DEFIBRILLATORS**

DEPARTMENTAL RECOMMENDATION

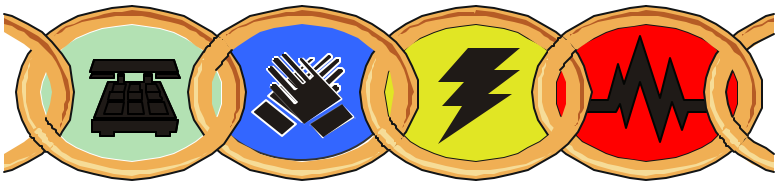
That Corporate Services and Economic Development Committee recommend Council approve the funding to the Base Hospital Program of Ottawa-Carleton for the immediate purchase of 35 Zoll Medical M Series Monitor / Defibrillators Multi-Pro Plus Model, and training on the new equipment for all paramedics currently working in Ottawa-Carleton, at a total cost of $930,312 (after trade-in). The Ministry of Health and Long-Term Care has agreed to fund $232,631 or 25% leaving the Region with the remaining 75% portion at a cost of $697,681.

INTRODUCTION

Medical research clearly indicates the importance of the *Chain of Survival* (illustrated below) in saving lives. Outcomes improve when the four links of the Chain are followed in sequence and as rapidly as possible.

While there have been many efforts in Ottawa-Carleton to improve the Chain, there is still much left to do. It is important to note that the common word in each of the four links is "Early".

Chain of Survival



Early defibrillation is the key link in the Chain of Survival for sudden cardiac arrest victims. Victims of sudden cardiac arrest are destined to die without prompt medical intervention including early defibrillation. Numerous scientific studies have proven that early defibrillation is the single most important factor affecting survival from sudden cardiac arrest.

The fourth link in the Chain is "Early Advanced Care". Like most other communities in Ontario, Ottawa-Carleton's Regional Council directed staff to work towards a full Advanced Life Support Paramedic system. Advanced Life Support Paramedics can mean the difference between life and death for sudden cardiac arrest patients.

BACKGROUND

The current defibrillators were purchased by the Ministry of Health several years ago (between 1994 and 1996) to be used by Primary Care Paramedics. Since then, and as a result of the Ontario Pre-Hospital Advanced Life Support study (the OPALS study) the Region of Ottawa-Carleton has been fortunate to have Advanced Care Paramedics available to the community.

The existing defibrillators are inadequate as a diagnostic and reporting tool for Advanced Care Paramedics. (Annex A illustrates this as reported by the Emergency Care Research Institute "Focus on Automatic External Defibrillators", May - June 1999).

The current defibrillators have reached the end of their safe serviceable life span, and are failing at an alarming rate. The cost of maintaining the existing defibrillators is $56,400 per year. The most recent letter to the Ministry, from the Base Hospital of Ottawa-Carleton dated 16 March 2000 is attached in Annex B.

DISCUSSION

To take full advantage of the highly skilled Advanced Life Support Paramedics in the Ottawa-Carleton community, new defibrillators with advanced technology are required.

The Base Hospital Program is the designated body of the Ministry responsible for medical direction in the pre-hospital care environment. The Advanced Life Support Equipment Committee, chaired by Base Hospital staff was tasked with the selection of the replacement defibrillators. The Committee was made up of representatives from: primary and advanced paramedics, Ottawa hospital bio-medical staff, the Medical Director, Ministry staff and Region of Ottawa-Carleton ambulance health services staff.

Of the four companies that responded to the request for new defibrillators, Zoll Medical Corporation's product was unanimously selected by the Committee to meet the needs of the community.

On 16 February 2000 the Committee sent a report to the Ministry and the Region outlining their recommendations for the "Zoll" defibrillator (Annex C).

The new defibrillators have time saving technology that eliminates paper work and allows report downloading to a desktop or laptop computer. The new machines also capture complete information, as opposed to only "snapshots" of information as with the current machines. The features included on the new machines have been judged to be medically necessary and beneficial in the pre-hospital care environment by the Medical Director, Dr. Justin Maloney. The type of monitor/defibrillator that has been proposed is accepted as an industry standard in most Advanced Care ambulance systems in North America.

On 10 March 2000 the Region wrote the Ministry advising again that: "… the existing units are continuing to have failures and pose a risk to the health of our community." and that: "The replacement of the existing defibrillator is a critical issue due to their decreasing reliability." The purpose of this letter was to confirm the Ministry's 50% cost sharing of this item (Annex D).

On 27 March 2000 the Region's Medical Officer of Health, Dr. Cushman wrote to advise the Ministry that the defibrillators needed to be replaced immediately (Annex E).

On 04 April 2000 the Ottawa Transition Board announced a freeze on the 2000 Capital Budget, Land Ambulance Transition project.

On 10 April 2000 the Ministry responded to the Region's request for 50% funding. The Ministry stated that the selected Zoll defibrillator exceeds the standards for the current Ministry defibrillator specification. Based on this, the Ministry has advised that its approved share of the funding is $232,631.00 (Annex F).

FINANCIAL COMMENT

In December 1999 Regional Council approved funds for the purchase of new defibrillators, estimated at a total cost of $900,000 in the 2000 Capital Budget, Land Ambulance Transition Project. The Budget in total was approved based on a 50/50 cost share with the Province.

The cost of replacement defibrillators is: $930,312 including the trade-in value of the existing defibrillators. The Ministry has advised that its share is $232,631 or about 25% of the total capital cost, leaving the Region with $697,681 or 75% of the cost.

FINANCIAL STATEMENT AND APPROVAL

	$
Approved Budget to Date	3,569,000
Total Paid and Committed	0
Balance Available	3,569,000
THIS REQUEST	(697,681)
Balance Remaining	2,871,319

Funds have been provided in the Year 2000 Ambulance Health Services Capital Transition Budget, Order No. 900453, Land Ambulance Transition Project (Reference Page 117).

CONCLUSION

The current defibrillators used by the Primary and Advanced Life Support Paramedics need to be replaced for the safety and benefit of the patient and the provider. The Ministry's standards on defibrillators are outdated. The defibrillators selected by the Committee are an accepted industry standard throughout North America and cannot be delayed any further.

The new defibrillators as recommended by the Advanced Life Support Equipment Committee are the first step in improving patient care for the residents and visitors to the Nation's capital over the next several years.

Approved by
Robert Cushman, MD, FRCPC

FINANCE DEPARTMENT COMMENT

Funding for the purchase of new defibrillator units was approved by Council in the 2000 Capital Budget, Land Ambulance Transition Project (Internal Order #900453). All costs identified in this project were assumed to be cost shared with the province on a 50 / 50 basis.

The Medical Officer of Health has indicated that the province is prepared to only fund 25% of the costs associated with the purchase of the defibrillators. As a result, the Region's share of the cost is estimated to increase by $232,525 - from $465,156 to $697,681. Funds are available for transfer from the Region Wide Capital Reserve Fund to fund the additional cost. The uncommitted balance in this Fund as of December 31, 1999, is approximately $2.8 million. This balance does not reflect the 1999 year end operating results of the Region Wide Operating Fund.

TRANSITION BOARD APPROVAL

The 2000 Capital Budget for the Land Ambulance Transition Project is currently under review by the Ottawa Transition Board. Approval for the purchase of the defibrillators and the transfer of funds from the Region Wide Capital Reserve Fund is subject to Board approval.

Approved by
J. C. LeBelle

ANNEX A

Evaluation

Ratings and Rankings by Model Name

HP Heartstream ForeRunner

Evaluated in this issue; see page 194. We tested the EM model, which includes an ECG monitor and a manual override button.

In-hospital use

- *Advanced as well as basic users.* Inappropriate. Although the unit has an ECG monitor and can be converted to a manual mode of operation for ALS users, it cannot be operated from AC line power, and it lacks other features present on conventional defibrillator/monitors (e.g., synchronized cardioversion, pacing).
- *Basic users only.* Acceptable, Group 1 (Units with an ECG Monitor). For this application, we consider this unit to be the best choice for purchasers who desire an AED with an ECG monitor. The unit performs well and is easy to use, very lightweight and portable, and relatively inexpensive. Also, it operates for a sufficient duration on battery power and requires minimal battery maintenance. One possible drawback is that the unit cannot be operated from AC line power — a capability that would be preferred for the in-hospital environment.

Prehospital use

- *PAD users.* Acceptable, Group 1. We consider this one of the top units for this application. In addition to being easy to use, small and lightweight, and relatively inexpensive, the unit performs daily self-tests and provides maintenance indicators that simplify device maintenance. Also, it can store ECG and event information. Of the three evaluated units that are appropriate for PAD, this is the only one that includes an ECG monitor, making it the best choice for users who desire this feature. (Note that the monitor is incorporated in a way that does not compromise the device's ease of use.)
- *First responders.* Acceptable, Group 1 (Units with an ECG Monitor). For the reasons described under "In-Hospital Use — Basic Users Only," we consider this model to be the best choice for first responders who desire a unit with an ECG monitor.

Laerdal Heartstart 3000QR

Evaluated in *Health Devices* 24(8-9), August-September 1995. No changes have been reported.

Legend

The figures on the following pages illustrate our application-specific ratings and rankings for each evaluated unit. We used the scheme defined below.

- Acceptable—Group 1
- Acceptable—Group 2
- Acceptable—Not Recommended
- Inappropriate for the application
- **ECG** For this application, the unit is ranked in comparison with other models that have ECG capability.
- **No ECG** For this application, the unit is ranked in comparison with other models that do not have ECG capability.

In-hospital use

- *Advanced as well as basic users.* Inappropriate. Although the unit has an ECG monitor and can be converted to a manual mode of operation for ALS users, it cannot be operated from AC line power, and it lacks other features present on conventional defibrillator/monitors (e.g., synchronized cardioversion, pacing).
- *Basic users only.* Acceptable, Group 2 (Units with an ECG Monitor). We ranked this unit in Group 2 because it is not quite as easy to use, as lightweight, or as inexpensive as the Group 1 unit.

Prehospital use

- *PAD users.* Inappropriate. This unit — which has an ECG monitor — is too heavy, too complicated, and too expensive for this application. It was not designed specifically for this use.
- *First responders.* Acceptable, Group 2 (Units with an ECG Monitor). We ranked this unit in Group 2 because it is not quite as easy to use, as lightweight, or as inexpensive as the Group 1 unit.

Marquette

Responder 1250

Evaluated in *Health Devices* 24(8-9), August-September 1995. No changes have been reported.

In-hospital use

- *Advanced as well as basic users.* Inappropriate. Although the unit has an ECG monitor and can be converted to a manual mode of operation for ALS users, it lacks other features present on conventional defibrillator/monitors (e.g., synchronized cardioversion, pacing).
- *Basic users only.* Acceptable, Group 2 (Units with an ECG Monitor). We ranked this unit in Group 2 because

ANNEX

The Ottawa Hospital | **Hôpital d'Ottawa**

General Campus Général

501 Smyth
Ottawa, Ontario
K1H 8L6

(613) 737-8999
Fax: 737-8008

Base Hospital Program
Ottawa-Carleton

Programme de base hospitalière
Ottawa-Carleton

March 16, 2000

Mr. Blake Forsyth
Regional Manager
Emergency Health Services Branch, Ministry of Health
75 Spring St., P.O. Box 790
Almonte, Ontario
K0A 1A0

Dear Blake:

Re: Defibrillator Failure Rates

In response to your March 13, 2000 e-mail correspondence, you are correct in assessing from our March 8, 2000 correspondence that there is little difference between the 1997 and 1999 failure rates. The failure rates were alarming in 1997 and 1999, and multiple correspondence from this office to Laerdal and the Ministry of Health (MOH), requesting action, have gone unanswered. Also, please note that the 2000 data provided was for the first two months of this year, only. There is an alarming failure rate, which if left unattended, will affect patient care and present an increased risk of litigation.

Based on the update received from Laerdal via Health Canada it appears that Laerdal will once again dilute the significance of device/component failures by incorporating devices employed throughout the worldwide market place. This does nothing to address our problem. As depicted in the graphs, high call volume services present with a higher failure rate. Hence, comparing failure rates from services other than those similar to ours is futile.

The base hospital chose to present these graphs to demonstrate that current defibrillator failure rates have been a problem since 1997. Reliability is an issue and does impact on patient care. As described in the graph, the performance failures are the most critical. In this phase you cannot treat a patient. The base hospital records show that there is a 10% performance failure rate of the current defibrillators. I am sure that the MOH cannot support a 10% failure rate. This is an unprecident failure rate.

The base hospital is currently providing on-going preventative maintenance, often replacing circuit boards at a rate of 2 to 3 per week. In the last week, the base hospital has documented 2 incidents in which an emergency vehicle on duty almost had to do without a defibrillator, due to alarming failure rates. What Laerdal sends back to the base hospital as replacement circuit boards, still have the same structural weakness that allowed the failure initially. The defibrillator will fail again. An example would be the energy storage capacitor, the rebuilt boards have no extra mounting hardware to prevent them from breaking off again. All this activity is costing the MOH serious replacement dollars and is only a band-aid solution.

Contrary to your statement that I did not like preparing the costs analysis the MOH requested in June 10, 1999, I understand that you must look closely at the funding implications. What I wanted to make absolutely clear to the MOH was that you cannot use the summary of equipment history as the sole indicator for approving a replacement defibrillator. The MOH must consider that the current defibrillators are:

- old,
- and are not appropriate for the level of care being provided to the pre-hospital patients in Ottawa.

Upon completing the current round of preventative maintenance an updated summary of equipment history will be forwarded to your office. (April 1, 2000).

Also enclosed, as requested, is a list outlining the required features of the proposed replacement defibrillator compared to the MOH semi-automatic defibrillator standard for Primary Paramedics Programs.

Finally, I cannot agree with you that we have time. The MOH takes a risk with each passing day. If the base hospital does not have a green light to replace the defibrillators by April 1, 2000, the base hospital cannot implement the new defibrillators until the fall of 2000. This means that during the high volume summer months, even more people will be at risk.

Sincerely,

Norma Boyd
Program Manager

Enclosure

cc: **Ms. Joanne Yelle-Weatherall, Director, Land Ambulance Services for the Region of Ottawa-Carleton**
Mr. Victor Simon, Chief Operating Officer, Ottawa Hospital, General Campus

defibfailurerates

General Campus Général

501 Smyth
Ottawa, Ontario
K1H 8L6

(613) 737-8999
Fax: 737-8008

Base Hospital
Program
Ottawa-Carleton

Programme
de base
hospitalière
Ottawa-Carleton

February 16, 2000

Ms. J. Yelle-Weatherall
Director, Land Ambulance Services
Region of Ottawa-Carleton
495 Richmond Road
Ottawa, Ontario K2A 4A4

Mr. B. Forsyth
Regional Manager, Ontario East
Emergency Health Services Branch
Ministry of Health
75 Spring Street, Almonte, Ontario K0A 1A0

Dear Ms. Yelle-Weatherall and Mr. Forsyth:

Re: Recommendation

Please find enclosed:
A Recommendation for Replacement of the Existing Monitor/Defibrillators Used by the Paramedics in the Regional Municipality of Ottawa-Carleton, and correspondence and a quote from Zoll Medical.

The Base Hospital Program of Ottawa-Carleton submits these documents for your review and direction, at your earliest opportunity.

Thank you for your attention to this issue.

Sincerely,

Norma Boyd

Norma Boyd
Program Manager

Enclosures

cc: Mr. Neil Johnston, Territory Manager, Zoll Medical Corporation

ANNEX C

RECOMMENDATION FOR REPLACEMENT OF THE EXISTING MONITOR/DEFIBRILLATORS USED BY THE PARAMEDICS IN THE REGIONAL MUNICIPALITY OF OTTAWA-CARLETON

Prepared by the Base Hospital Program of Ottawa-Carleton

Prepared for:

Joanne Yelle-Weatherall
Director
Land Ambulance Services
Region of Ottawa-Carleton

Blake Forsyth
Regional Manager
Emergency Health Services Branch
Ministry of Health

Date of submission: February 16, 2000

1. Introduction/Recommendation:

The current defibrillators used by the Primary and Advanced Paramedics of the Region of Ottawa-Carleton (ROC) need to be replaced for the safety and benefit of the patient and provider.

The Advanced Life Support (ALS) Equipment Committee of the Base Hospital Program (BHP) of Ottawa-Carleton (O-C) is pleased to submit a unanimous recommendation for the replacement of the defibrillators currently in use by the Primary and Advanced Paramedics of the ROC.

The recommendation is a follows:
The immediate purchase of thirty-five (35) Zoll Medical M Series Defibrillators Multi-Pro Plus Model #41421211100163010, at a cost of $930,305.60 which includes training and implementation in the field.

The following information will detail how the Equipment Committee of the BHP-OC not only came to the unanimous recommendation, but how the proposed new defibrillator is medically sound and necessary.

2. Needs Analysis:

The current defibrillator inventory and history as provided by the Bio-Medical Department of the Ottawa Hospital, General Campus indicates that the average age of the existing defibrillators are 5 years. These defibrillators where purchased by the Emergency Health Services Branch (EHSB) of the Ministry of Health (MOH) to be used in a Primary Paramedic setting only.

The Emergency Care Research Institute (ECRI) **<ref Focus on AEDs; Health Devices 28 (5-6), May – June 1999>** has graded the current defibrillator as unacceptable for Advanced Paramedic providers in hospital. This report did indicate that this defibrillator was acceptable for Primary Paramedic and First Responder services.

Usage profiles, service history and age dictate the need for replacement. The following outline details the need for replacement:

- Advanced Paramedics place more demands on the current defibrillator by increasing the frequency of overall use. Including monitoring a greater population of patients, more electrocardiograph recordings as well as shocking more often.
- Since 1995 there has been a steady increase in the number of Advanced Paramedics. To date there are 78 Advanced Paramedics employed throughout the Region of Ottawa-Carleton.
- Limitations of the current technology dictates that call reports are transcribed via the defibrillator. Current drain from the battery is doubled upon recording, hence it greatly impacts on useful battery life. The proposed new defibrillator technology addresses this through state-of-the-art PC cards, which will be downloaded into computers, provided by the company.
- Increased use of defibrillators designed for Primary Paramedic providers along with ageing equipment have reached 20% component related failures for the last few years. (Appendix VI). This finding is compared to board failure rates of 6.1% for all other units employed throughout Fire Departments and Associate Base Hospital Programs.
- This same scenario has caused an increase of 501% and 344% service demands on batteries and defibrillator maintenance times (Appendix VII).
- Specific component failures such as transfer relays, capacitors, R28, and R121 are presenting themselves as stress related failures. Within this high level service these problems will continually increase.
- Currently, repair and maintenance cost totals $28,221.00 for ROC only.

While specific guidelines pertaining to re-capitalisation do not exits, there is literature supporting the need for replacement as early as 6 years or when the service demands extend beyond the capabilities of the unit <ref. Cummons RO, Chesemore K, White RD, JAMA 1990 Aug 22-29; 264(8):1019-25> <ref. The Emergency Care Research Institute (ECRI), Focus on AEDs; Health Devices 28 (5-6), May – June 1999.

3. Goal for Replacement Defibrillators:

The goal of the replacement defibrillators is to provide a system better equipped to deliver pre-hospital advanced life support care to critically ill or injured patients.

4. Objectives for Replacement Defibrillators:

a. To provide risk management of essential patient care equipment.
b. To eliminate increasing persistent shortcomings in the current defibrillators.
c. To provide a more efficient and cost effective use of oxygen therapy and supplies by paramedics.
d. To drastically improve data management documentation during use of the defibrillator in the pre-hospital field.
e. To provide the Advanced Paramedic with the appropriate tools to their level of training.
f. To provide improved quality assurance tools for the Medical Director certifying paramedics under his/her license.

5. Process for Establishing the Recommendation:

The following is the process undertaken by the BHP of OC to establish the recommendation to replace the existing defibrillators:

The BHP of O-C established an Advanced Life Support Equipment Committee, with a clear mandate, purpose, terms of reference and membership (Appendix I). The membership of this committee brought together administrators, a physician, bio-medical staff, and end users of the proposed product.

a. The committee outlined and reviewed the existing defibrillator shortcoming, history, and maintenance costs.

b. The committee developed a questionnaire sent out to all paramedics in the field for their input on the present defibrillators. (Appendix III)

c. The committee undertook a market search for a replacement defibrillator of the following companies, and requested a total of 2 quotes from each: Zoll Medical, Physio-Control, MRL PIC System, and Hewlett-Packard.

d. The committee organised a presentation and demonstration of each of the above mentioned company defibrillators. Static displays after all presentations allowed for adequate question and answer period for committee members.

e. Following the presentation and demonstration to the committee members, the multiple displays were provided to all paramedics in an "open house". Paramedics that attended completed a survey on the displays. (Appendix IV)

f. The committee members retained all four defibrillators for one month at the base hospital office and analysed each machine in 16 separate categories.

g. At the end of the month the committee members voted on the defibrillators and their quotes in 16 categories to determine their unanimous recommendation (Appendix V).

Introduction/Recommendation:

Current defibrillators used by the Primary and Advanced Paramedics of the Region of Ottawa-Carleton (ROC) need to be replaced for the safety and benefit of the patient and provider.

The Advanced Life Support (ALS) Equipment Committee of the Base Hospital Program (BHP) of Ottawa-Carleton (O-C) is pleased to submit a unanimous recommendation for the replacement of the defibrillators currently in use by the Primary and Advanced Paramedics of the ROC.

The recommendation is a follows:
The immediate purchase of thirty-five (35) Zoll Medical M Series Defibrillators Multi-Pro Plus Model #41421211100163010, at a cost of $930,305.60 which includes training and implementation in the field.

The following information will detail how the Equipment Committee of the BHP-OC not only came to the unanimous recommendation, but how the proposed new defibrillator is medically sound and necessary.

2. Needs Analysis:

The current defibrillator inventory and history as provided by the Bio-Medical Department of the Ottawa Hospital, General Campus indicates that the average age of the existing defibrillators are 5 years. These defibrillators where purchased by the Emergency Health Services Branch (EHSB) of the Ministry of Health (MOH) to be used in a Primary Paramedic setting only.

The Emergency Care Research Institute (ECRI) **<ref Focus on AEDs; Health Devices 28 (5-6), May – June 1999>** has graded the current defibrillator as unacceptable for Advanced Paramedic providers in hospital. This report did indicate that this defibrillator was acceptable for Primary Paramedic and First Responder services.

Usage profiles, service history and age dictate the need for replacement. The following outline details the need for replacement:

- Advanced Paramedics place more demands on the current defibrillator by increasing the frequency of overall use. Including monitoring a greater population of patients, more electrocardiograph recordings as well as shocking more often.
- Since 1995 there has been a steady increase in the number of Advanced Paramedics. To date there are 78 Advanced Paramedics employed throughout the Region of Ottawa-Carleton.
- Limitations of the current technology dictates that call reports are transcribed via the defibrillator. Current drain from the battery is doubled upon recording, hence it greatly impacts on useful battery life. The proposed new defibrillator technology addresses this through state-of-the-art PC cards, which will be downloaded into computers, provided by the company.
- Increased use of defibrillators designed for Primary Paramedic providers along with ageing equipment have reached 20% component related failures for the last few years. (Appendix VI). This finding is compared to board failure rates of 6.1% for all other units employed throughout Fire Departments and Associate Base Hospital Programs.
- This same scenario has caused an increase of 501% and 344% service demands on batteries and defibrillator maintenance times (Appendix VII).
- Specific component failures such as transfer relays, capacitors, R28, and R121 are presenting themselves as stress related failures. Within this high level service these problems will continually increase.
- Currently, repair and maintenance cost totals $28,221.00 for ROC only.

6. Proposed Replacement Plan:

The following is the proposed replacement plan of the current defibrillators:

- Approval and purchase order of 35 Zoll Medical M Series Defibrillators by April 1, 2000.
- Instructor training by Zoll Medical staff of the new defibrillator in May 2000.
- New defibrillator received by the Bio-Medical Department of the Ottawa Hospital, General Campus by mid June 2000 for inspection.
- 8 hour orientation and training session of the new defibrillator to all Primary and Advanced Paramedics in joint 16, 8 hour session starting the last week of May, 2000 and ending in June, 2000.
- Release all new defibrillators on the day after the last training sessions, and collect the old defibrillators.

7. Budget:

Description	Costs
35 Zoll Medical Monitor Defibrillators without Trade-in	$876,754.40
Training of 8 Instructor Trainers for 8 hours at $25.00 per hours	$3,200.00
Bio-Medical costs for initial inspection of new defibrillators at $60.00 per hour	$3,150.00
Bio-Medical Costs for preventative maintenance and repair for 35 defibrillators for year 1	$4,150.00
3 Instructors for 16, 8 hour sessions at $25.00 per hour	$9,600.00
Replacement costs for 210 Primary Paramedics and Supervisors at $18.84 per hour	$31,651.20
Printing costs for training program on new defibrillators at $6.00 per student for a total of 300 copies	$1,800.00
TOTAL	$920,305.60

8. Bio-Medical Support:

It is proposed that the Bio-Medical Department of the Ottawa Hospital General campus will continue to provide the bio-medical support of the proposed new defibrillators. Currently it takes 30 minutes per preventative maintenance procedure. The defibrillators are serviced twice a year, and have an annual maintenance cost of $60.00 per defibrillator.

Time requirements for maintaining the proposed new defibrillator will be 45 minutes per unit. It is recommended that preventative maintenance be performed twice a year at an annual cost of $90.00 per defibrillator.

The BHP of OC is currently funded for bio-medical support by the EHSB of the MOH, for the existing defibrillators.

Zoll Medical will be providing the Bio-Medical Department with training in the care of the defibrillators. As well, replacement parts will be provided to the Bio-Medical Department to eliminate the delays for parts.

9. Quality Assurance and Reporting:

The following will be the quality assurance and reporting of the proposed new defibrillators:

- Report on inspection of proposed new defibrillators.
- Computerised service history of each defibrillator from the moment of purchase.
- Report on the training provided to Instructors and Primary and Advanced Paramedics.
- Quarterly report on any problems encountered with the proposed new defibrillators in the first year of operation.
- Bi-annual reports on preventative maintenance during the life of the proposed new defibrillators.
- Bi-annual reports on any problems with the proposed new defibrillators after the first year.

10. Training in the use of the proposed new defibrillator:

The BHP of OC will organise, deliver and report on the orientation and training of the proposed new defibrillator of all Primary and Advanced Paramedics and management currently working in ROC. These 300 individuals will attend one 8 hour session, which will be provided 16 times. The average class size will be no greater than 18, with 3 instructors per class. A total of 8 individuals will be trained to provide the training.

The BHP of OC proposes to use the current "Elective Continuing Medical Education" 8 replacement hours of the Advanced Paramedics, and has submitted for replacement 8 hours for all Primary Paramedics in the budget herein.

11. Trade in of Existing Defibrillators:

Zoll Medical is willing to provide $1,788 for each existing defibrillator as part of a trade in, as described in their quote. This action will require the approval of the EHSB of the MOH, and the ROC.

12. Data Collection from First Responders and Other Defibrillators in Use:

First responders in ROC will continue their current practice of providing the paramedics with their data collection device in exchange for a new one by the paramedic. The data collected by the first responder will be printed by the base hospital office and joined to the call information. Out of town ambulance vehicles or other public access defibrillators will also follow current practice and protocols and the ROC paramedics will continue to obtain their data as currently expected.

Conclusion:

The BHP of O-C is confident that the process that lead to the recommendation to purchase Zoll Medical defibrillators is complete, fair, and medically sound. Although many issues demand the attention of administrators of the ROC and the EHSB, MOH, the base hospital urges your prompt review and approval of this recommendation. Changing the defibrillators will benefit the patient.

APPENDIX I

ADVANCED LIFE SUPPORT EQUIPMENT COMMITTEE
BASE HOSPITAL PROGRAM, OTTAWA-CARLETON

Reason for Committee:
The Advanced Life Support Equipment Committee (ALSEC) is a standing committee of the Base Hospital Program (BHP), Ottawa-Carleton. The Base Hospital Program is mandated by contract with the Emergency Health Services Branch (EHSB) of the Ministry of Health (MOH) to provide the medical equipment and supplies required for the delivery of the delegated medical acts authorised by the MOH. Furthermore, the BHP is mandated to provide maintenance, quality improvement and quality assurance on equipment to ensure reliability.

Purpose for Committee:
The purpose of the committee is to enhance and/or replace the current ALS equipment as needed in order to deliver the Ministry approved delegated medical acts as approved by the Medical Director, EHSB (MOH), and the Regional Municipality of Ottawa-Carleton Land Ambulance Services.

Terms of Reference:
To provide a forum for discussion, data collection, medical reliability, medical usefulness, and too make recommendation on equipment acquisitions with regards to quality assurance and quality improvement.

Membership of Committee:
Mr. Andrew Orchard, BHP O-C, Advanced Life Support Co-ordinator (Chair)
Ms. Joanne Yelle-Weatherall, Director, Land Ambulance Services, RMOC or designate
Dr. Justin Maloney, BHP O-C, Medical Director
Mr. Mark Cleland, Bio-Med Department, Ottawa Hospital, General Campus
Mr. Joe Micucci, BHP O-C, Primary Life Support Co-ordinator
Mr. Lyle Massender, Manager, Ottawa-Carleton Regional Ambulance Service
Two (2) Advanced Paramedics (Mr. James Ide, Ms. Lise Laporte) Alt. Mr. Marc Landriault)
Two (2) Primary Paramedics (Mr. James Smith, Ms. Donna Duff) Alt. Ms. Linda Blackman)

cc: Mr. Blake Forsyth, Regional Manager, EHSB, MOH

The meetings are open to all related providers for observation only. Input is welcomed via committee members.

Voting Members:
Each committee member or their designate will hold one (1) vote. Tie votes will be broken by an additional vote from the Chair.

Duties and Responsibilities of Members:
- Provide an alternate to attend the meeting if a member is unable to do so. Provide orientation to the alternate.
- Be responsible for ensuring communication with the agencies/groups the member represents.
- Be prepared to provide motions on issues discussed, and to provide reports as required.
- Participation is voluntary.
- Members may not be employees or subcontractors of any medical equipment supplier.

TERM:
Committee members shall serve a two (2) year term. Consecutive terms are permitted.

APPENDIX II

MINIMUM STANDARDS FOR EXTERNAL DEFIBRILLATOR

1. Normative Reference and Definitions

Where applicable all normative references and technical definitions used in this specification will be considered to be reflected in the ANSI/AAMI DF2-1996 standard as developed by the Association for the Advancement of Medical Instrumentation and as approved on the 29th day of April, 1996 by the American National Standards Institute.

1.1 Scope

This specification applies only to external defibrillators which will have the physical and performance characteristics set out below.

1.2 Device

For the purposes of this specification a "device" will be defined as being a manual external defibrillator.

1.3 Biomedical Engineering Department

For the purposes of this specification the Biomedical Engineering Department of the Ottawa Hospital shall de defined as the agency or organisation that is contracted by a Base Hospital to provide the biomedical preventative maintenance and servicing of the defibrillators.

2. Defibrillator Device Requirements

The device shall meet all of the following requirements:

2.1 Device

The device is a battery powered, portable, external defibrillator with integrated paper event documentation and with a separate electronic medical event documentation unit.

The device shall have the appropriate Canadian Standards Association (CSA – C22.2) or IEC 601.2.4-M90 approval.

The device shall have the appropriate United States, Food and Drug Administration or equivalent medical device approval for use in a clinical application.

2.2 Labelling

Each device, battery charger, and defibrillation electrode will have all labelling as set out in Subsection 3.1 of the ANSI/AAMI DF2-1996 standard noted above.

2.3 Operating Instructions

Each device will be supplied with 1 copy of the full operating instructions for the device. The operating instructions will comply with Subsection 3.2 of the ANSI/AAMI DF 2-1996 standard noted above.

2.4 Maintenance & Service Manuals

Biomedical Engineering Department, responsible for preventative maintenance and servicing of the device will be supplied with two (2) copies of the maintenance and service manuals for the device. These manuals will include the electrical/electronic schematic of the device. The maintenance and service manuals will comply with Subsection 3.2 of the ANSI/AAMI DF2-1996 standard, as well as, the requirements established by the Biomedical Engineering Department of the Ottawa Hospital (Appendix B).

3. Essential Requirements of Each Device

3.1 Operating Conditions
In addition to meeting all of the conditions set out in Subsection 3.3.1 of the ANSI/AAMI DF 2-1996 standard, the vendor must warrant the device for use in the operating temperature range of between minus five (-5) degrees Celsius and plus fifty (+50) degrees Celsius.

3.2 Energy Range
In addition to meeting all of the conditions set out in Subsection 3.3.2 of the ANSI/AAMI DF 2-1996 standard, a maximum of 360 joules of energy will be delivered with each discharge by the device. This includes defibrillators employing biphasic waveform technology.

Energy settings will be user programmable and will at a minimum provide for three (3) settings between 100 and 360 joules inclusive (biphasic waveforms, the energy settings may be 100, 100, 130J). The device will be capable of complying with the recommended energy setting standards of the American Heart Association. See appendix A for the American Heart Association's energy requirements.

3.3 Energy Accuracy
The device will meet all of the conditions set out in Subsection 3.3.3 of the ANSI/AAMI DF2-1996 standard.

3.4 Pulse Shape and Duration
In addition to meeting all of the conditions set out in Subsection 3.3.4 of the ANSI/AAMI DF2-1996 standard noted above, the vendor shall document the type of waveform utilised by their device. Devices employing biphasic waveform technology refer to reference #2 listed in Appendix A.

3.5 Charge Time
The device will meet all of the conditions set out in Subsection 3.3.5 of the ANSI/AAMI DF2-1996 standard.

3.6 Battery Capacity
In additional to all of the conditions set out in Subsection 3.3.6 and applicable part of Subsection 3.3.7 of the ANSI/AAMI DF2-1996 standard, a new fully charged battery used in a defibrillator, operating at four (4) degrees Celsius will deliver fifteen (15) consecutive discharges of 360 joules. The battery should possess capacity will be able to provide a minimum of three (3) hours of patient monitoring following which the battery will be able to deliver three (3) consecutive discharges of 360 joules.

3.7 Energy Loss Rate
The device will meet all of the conditions set out in Subsection 3.3.8 of the ANSI/AAMI DF2-1996 standard.

3.8 Automatic Disarm
The device will meet all of the conditions set out in Subsection 3.3.9 of the ANSI/AAMI DF2-1996 standard.

3.9 Controls and Indicators
The device will meet all of the conditions set out in Subsection 3.3.10 of the ANSI/AAMI DF2-1996 standard.

The device will be equipped with a real time clock, which is capable of being adjusted by the user.

3.10 Energy Level Indicator
The device will meet all of the conditions set out in Subsection 3.3.11 of the ANSI/AAMI DF2-1996 standard.

3.11 Charge Indicator
The device will meet all of the conditions set out in Subsection 3.3.12 of the ANSI/AAMI DF2-1996 standard.

3.12 Low Battery Charge Indicator
The device will meet all of the conditions set out in Subsection 3.3.13 of the ANSI/AAMI DF2-1996 standard.

3.13 Disarm
The device will meet all of the conditions set out in Subsection 3.3.16 of the ANSI/AAMI DF2-1996 standard.

3.14 Defibrillator Protection, Recovery, Energy Shunting, Operator Safety
The device will meet all of the conditions set out in Subsection 3.3.17 of the ANSI/AAMI DF 2-1996 standard.

3.15 Event Documentation
The device will meet all of the conditions set out in Subsection 3.3.20 of the ANSI/AAMI DF 2-1996 standard.

An elective event marker for user referencing of events shall be provided by the device.

In the event of equipment related failure an error message or code must appear on the unit's display, as well as, any real time recordings or event documentation to ensure the chart reviewer is aware that an equipment failure had occurred.

3.16 Electromagnetic Compatibility
The device will meet all of the conditions set out in Subsection 3.3.21 of the ANSI/AAMI DF 2-1996 standard.

3.17 Self-adhesive Electrodes for Monitoring and Defibrillation
The self-adhesive monitoring and defibrillation electrodes intended for use with the device will meet all of the conditions set out in Subsection 3.3.19 of the ANSI/AAMI DF 2-1996 standard.

The self-adhesive electrodes intended for monitoring only will meet all of the conditions set out in Subsection 3.3.19 of the ANSI/AAMI DF 2-1996 standard.

Each self-adhesive monitor/defibrillation electrode intended for use with the device will provide a minimum of 80 cm^2 of active patient/gel contact area.

The self-adhesive monitor/defibrillation electrodes intended for use with the devise will exhibit zero (0) gel migration within or on the electrode.

3.18 Cables
In addition to meeting all of the conditions set out in subsection 3.3.19.12 the cables will be fully shielded. Cables of single unit (one piece) construction are preferred.

Each device will be supplied with one (1) set of defibrillation/monitoring cables.

3.19 Electronic Medical Documentation Units
In addition to documenting all information covered under 3.16 of this specification, the unit, for electronically recording medical documentation for each patient, shall be designed so that it can be removed from the device for medical quality assurance purposes and readily replaced by a similar replacement unit.

3.20 Monitoring Characteristics
The device shall have a visual display that will enable the user to see clearly in all ambient lighting conditions a clear representation of the electrocardiogram of a patient (in one or more leads). In addition the visual display will permit easy visualization for printed warnings, prompts and messages being displayed.

The monitor should be capable of display electrocardiographic information at various bandwidth settings for accurate representation of the signals.

3:21 Batteries
The vendor will provide a listing of battery chemistries available for use with their defibrillator. The vendor will provide one battery per defibrillator upon the selection of the battery chemistry. Regardless of the battery type the specifications illustrated in section 3.6 of this document must be met.

The vendor must accept defective batteries for appropriate recycling at their cost.

3.22 Battery Chargers / Management Systems
A listing of battery chargers and or battery management systems (where applicable) must be provided. Upon selection of the battery chemistry the vendor will provide the appropriate charger or battery management system.

3.23 Paper Recording
Each device must be provided with a capability to provide continuous paper recording of a patient's electrocardiogram and other medical event documentation as required by this specification.

The recorder should be capable of producing real time recordings in a diagnostic bandwidth.

3.24 Carrying Case
Each device will be provided with a soft-side carrying case. The carrying case will be capable of carrying the device, two (2) pair of defibrillator electrodes, two (2) pair of monitoring electrodes, one (1) spare battery, one (1) spare electronic medical documentation unit and two (2) spare rolls of recording paper.

The carrying case shall be of a design such that portions of the carrying case cannot become detached from the body of the carrying case.

The carrying case shall be of a design such that the contents of the carrying case will not spill from the carrying case during normal use.

The carrying case shall be of a design and constructed of a material that will permit machine washing of the carrying case. The carrying case shall be capable of meeting the United States standard from the Occupational Health and Safety Administration of the cleaning of blood and body fluids.

3.25 Training Support
The vendor shall have completed instructor training on the device within 90 days of an order being placed. The training shall take place locally and travel costs shall be incurred by the vendor.

The training delivery methodology and quality is important.

The vendor shall provide educational advice and support to instructors involved in the preparation and certification of users of the device.

3.26 Simulator/Testers
The vendor shall provide ECG/defibrillator simulator/tester units that are compatible with the device being supplied.

3.27 Service
The vendor will ensure that the biomedical service centre receives a consignment of parts necessary for routine maintenance of the device and its accessories.

The vendor will ensure that the biomedical service centre receive all service documents and bulletins, recalls, notices or upgrades as they are issued by the manufacturer.

The vendor will provide specific test, analysis or diagnostic fixture or instrument that is required exclusively for the vendor's product (s).

The vendor will provide to the biomedical service centre, factory quality training, to manufacturers' standards in the maintenance and servicing of the vendors' product(s)

The vendor will, within 7 days of receiving a written request from a Base Hospital for clinical justification of the algorithm for their device, provide to the Medical Director, a full explanation of the response of their device to a specific clinical situation. A sample response to a clinical inquiry of the response of the algorithm, used in the device, to a failure to shock incident must be submitted as part of the proposal. Reference Medical device Recall (MDR) as published in the Canadian Gazette, May 1999.

3.28 Weight
The weight of each device including a soft-side carrying case, one (1) spare set of cables, two (2) pair of defibrillator electrodes, two (2) pair of monitoring electrodes, one (1) spare battery, one (1) spare electronic medical documentation unit and two (2) spare rolls of recording paper shall not exceed total package weight of ten (10) kilograms (22 lbs.).

Weight of the device is a significant ergonomic factor for potential users.

APPENDIX A

According to the American Heart Association "the recommended energy for the first defibrillation attempt is 200J. the energy level for second shocks should be 200 to 300J. If the first two shocks fail to defibrillate, a third shock, of 360 J, should be delivered immediately. Recommended initial energy for atrial fibrillation is 100J and for atrial flutter and PSVT, 50J, with stepwise increases in energy if initial shocks fail." [1] In the event a device employs a Biphasic output waveform, the following AHA Scientific Statement shall be used as reference[2]

1. "Chain of Survival" reprinted from the Journal of the American Medical Association, October 23, 1992, Volume 268, Number 16, pages 2211 & 2212.

2. Kerber RE, Becker LB, Bourland JD, et al ; Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety. Biomedical Instrumentation & Technology; May/June 1997; 238-244.

APPENDIX B:

What are the Ottawa Hospital's requirements for Medical Device (including Laboratory and Imaging apparatus) Service Manuals?

From our perspective a service manual should include <u>at least</u> the following:

1- General information (including full equipment specifications) and installation instructions.

2- A section that describes the theory of operation of the device(s).

3- A section that describes the procedures, references and tools used in installation, set-up and calibration of the device(s), including a list of required test equipment.

4- A section that describes troubleshooting methodology, diagnostic utilities (including access passwords), error codes, component location and schematic diagrams. Where applicable, diagnostic software packages shall be included.

5- If not included in 4-, all schematic diagrams and component layouts.
A comprehensive parts list showing exploded parts diagrams and cross referenced parts list(s).

If the equipment supplied incorporates OEM (Original Equipment Manufacturer) subassemblies, a full documentation package as specified above for these units shall be included. Typically, OEM assemblies are power supplies, display monitors, printer modules etc.

If required, Biomedical Engineering will sign a non-disclosure agreement to obtain service documentation.

In case the user (or operator's) manual includes all of the above, we will require two such manuals. One for the user, one for the Biomedical Engineering Department.
In those cases we will accept complete parts lists etc. at our discretion.
<u>Please note</u> that in these cases Biomedical Engineering will have to approve any deviation of these requirements <u>in advance</u>.

It is also imperative that the <u>service manuals be received with the equipment purchased</u>.
Only original documents are acceptable. We do not accept photocopies of manuals.

If service manuals are not included in the shipment, or are not to our specification, we may (at our option) reject the shipment, or withhold payment until our requirements are met.
For further information please call Mr. Ed Teolis, Manager, Biomedical Engineering, The Ottawa Hospital – General Campus at (613) 737-8516.

Voting Criteria

- Purchase Cost
- Warranty terms & conditions
- Device Features:
- Event documentation:
- What type of electronic storage device are they using, MCM, PCMCIA cards, RAM Memory.
- Electrodes:
- Connector - Does it make any right angle bends?
- Cabling – Are the patient cables shielded?
- Do the cables provide an adequate amount of insulation?
- Electronic recording (documentation):
- Transcription – what is the recording format (standard or compressed).
- Monitoring characteristics
- Screen type – LCD, EL, CRT.
- Layout of information – not too cluttered – good ergonomics.
- Battery system:
- The battery system must fit the defined end use.
- Paper recording
- Thermal array recorder: Paper size – Are we able to second source the paper?
- Carrying Case:
- Does it hold all required supplies?
- Will it compromise stored electrodes?
- Weight
- Ease of operation
- Quality of service / instruction documentation
- Service history (references)
- Protocol for dealing with Clinical Inquiries
- Compliance
- Total.

Prepared by: Mr. Mark J. Cleland BMET
Biomedical Engineering
Ottawa Hospital, General Campus
January, 2000

APPENDIX III

QUESTIONNAIRE

The Advanced Life Support Equipment Committee (ALSEC) is a standing committee of the Base Hospital Program (BHP), Ottawa-Carleton. The Base Hospital Program is mandated by contract with the Emergency Health Services Branch (EHSB) of the Ministry of Health (MOH) to provide the medical equipment and supplies required for the delivery of the delegated medical acts authorised by the MOH. Furthermore, BHP is mandated to provide maintenance, quality improvement and quality assurance on equipment to ensure reliability.

This committee is looking for a replacement for the current defibrillator. Over the next 4-6 months, the committee will make a recommendation to the BHP. A Proposal will then be forwarded to the Ministry of Health and to the Region of Ottawa-Carleton to replace the current model. The new model must be suitable for cardiac monitoring and defibrillation in the advanced life support prehospital setting. We will also provide a recommendation on Pulse Oximeters for use by Paramedics.

This committee is interested in receiving your input. Please provide in writing your concerns, suggestions, and recommendations. When possible provide facts not opinions, as we will use your input. We require input on the following topics:

Concerns or positive features of the current model.

List "musts" for new monitor/defibrillator, and any reasons why they must have these features.

Paddles versus pads to deliver shock for both Primary and Advanced paramedics. What is your preference, and why?

Should we have one monitor/defibrillator for the Advanced Paramedics, and one for the Primary Paramedic, or the same defibrillator for all?

Should we have Pulse Oximeters for just Advanced Paramedics, or for both Primary and Advanced Paramedics?

Why?

Should Pulse Oximeters form part of the monitor/defibrillator or be separate piece of equipment?

What should be the maximum weight of the monitor/defibrillator?

Please respond via: fax (737-9008), Base Hospital white boxes, or e-mail (als.coordinator@bh.ogh.on.ca)

The Base Hospital Program appreciates your time and input.

APPENDIX IV

ADVANCED LIFE SUPPORT EQUIPMENT COMMITTEE
BASE HOSPITAL PROGRAM, OTTAWA-CARLETON

EQUIPMENT SURVEY

DECEMBER 9, 1999

Please complete this survey, once you have assessed the four manufactures and their monitor/defibrillators. Your response will from a portion of our overall evaluation. Leave your completed copy in the provided survey box.

1) What is your fist choice for a monitor/defibrillator for a B.L.S. and A.L.S. system?

Why?

2) What is your second choice for a monitor/defibrillator for a B.L.S. and A.L.S. system?

Why?

3) Are any of the presented monitor/defibrillators not acceptable for a B.L.S. and A.L.S. setting?

YES / NO

List and explain why.

APPENDIX V

ADVANCED LIFE SUPPORT EQUIPMENT COMMITTEE

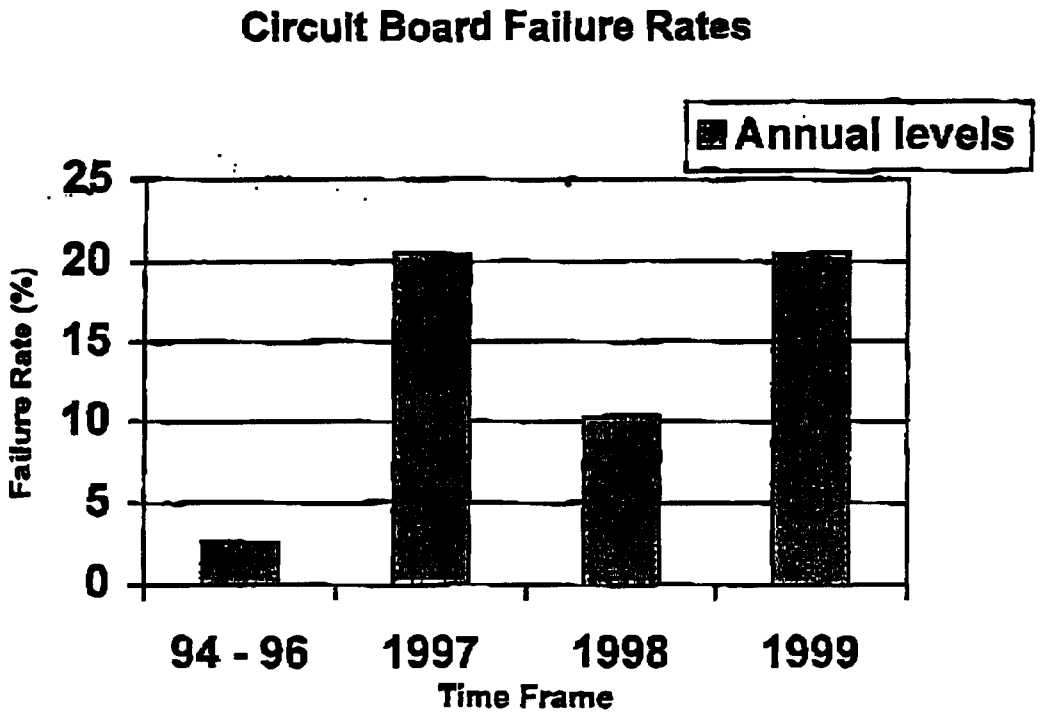
BASE HOSPITAL PROGRAM, OTTAWA-CARLETON

VOTING CRITERIA

DESCRIPTION	COMPLIANCE	PRIORITY	TOTALS
MONITORING CHARACTERISTICS: Screen type – LCD, EL, CRT. Screen layout not cluttered –good organomics. Multiple lead select Ability to set alarms		3	
EVENT DOCUMENTATION: Electronic storage – MCM, PCMCIA card, RAM memory		1	
ELECTRODES: Any weak connections/Cabling – Are cables shielded? Different weight cables, monitor vs defib. Pads vs paddles.		1	
ELECTRONIC RECORDING (DOCUMENTATION): Transcription – recording format Standard/Compressed Event recorder Documentation system, data download, report generator		2	
PAPER RECORDING: Thermal array recorder; Paper size – Secondary source		1	
BATTERY SYSTEM: Battery load adequate for intended use. Secondary source		2	
PEDIATRICS: Set joules for Ped. Patients Defibrillation electrodes		1	
CARRYING CASE: Holds required equipment Adequate protection of pads/equipment Durability/cleaning easy		2	
ABILITY TO UPGRADE:		1	
EASE OF OPERATION:		1	
WEIGHT OF TOTAL PACKAGE:		3	
SERVICE MAINTENANCE: Quality of service Service history (references) Turn around/replacement commitment Spares (1/10), Loaners Bio Med Support Canadian Support Office/depot Protocol for dealing with clinical inquiries		1	
TEACHING/TRAINING ASSISTANCE: AV aids Rhythm generators Self teaching videos, computer programs Funded speakers		1	
PACKAGE COST WITH BUYBACK CURRENT MODEL:		1	
WARRANTIES TERMS AND CONDITIONS:		1	
PARAMEDIC SURVEY:		1	
GRAND TOTALS:			

APPENDIX VI

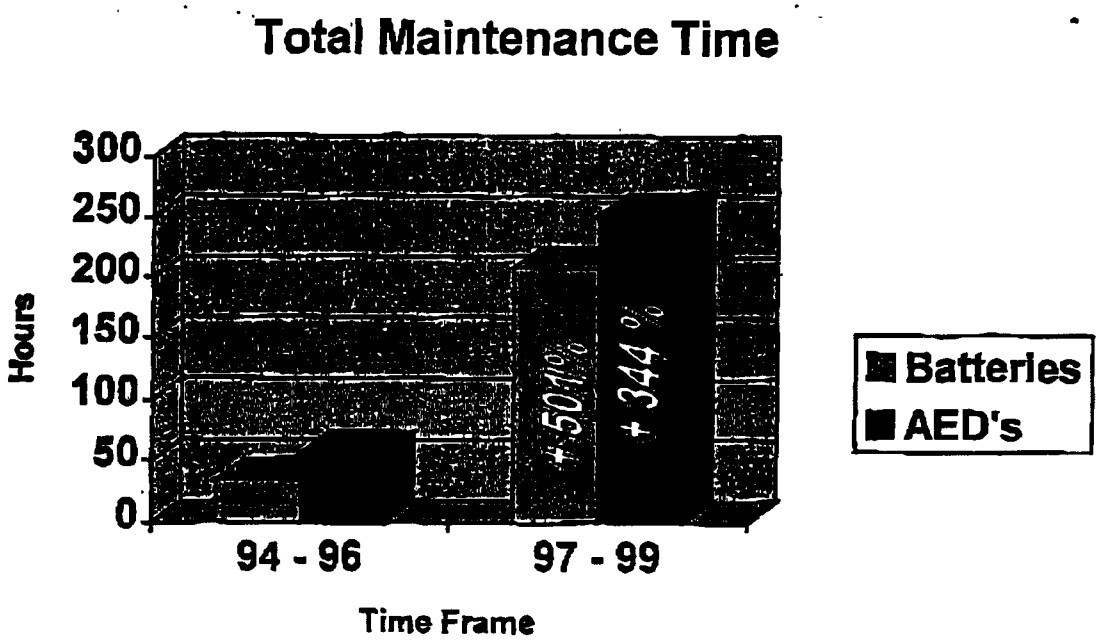
Figure 1: A graph depicting the increase in circuit board failures within the HS 3000 defibrillators employed throughout the Base Hospital Program of Ottawa-Carleton geographical jurisdiction.



Failure rate was calculated per year based on the number of defective circuit boards removed from the serviced defibrillators divided by the total number of defibrillators employed by the service (39).

APPENDIX VII

Figure 2: A graph illustrating the increase maintenance times for the pre (1994 to 1996) / post (1997 to 1999) warranty period.



Regional of Ottawa-Carleton
495 Richmond Road, 7th Floor
Ottawa, ON K2A 4B2

Health Department
Land Ambulance Services
Tel. (613) 560-6053 x2612
Fax. (613) 724-4124

Région d'Ottawa-Carleton
495, chemin Richmond, 7 étage
Ottawa (ON) K2A 4B2

Service de la Santé
Services d'ambulance terrestre
Tél. (613) 560-6053 x2612
Télécopieur (613) 724-4124

10 March 2000

File: 12-99-0008

Mr. Blake Forsyth
Regional Manager
Emergency Health Services Branch, East Ontario
Ministry of Health and Long-Term Care
75 Spring Street, P.O. Box 790
Almonte, Ontario
K0A 1A0

Dear Mr. Forsyth:

Re: Defibrillator Replacement Recommendation

We have received the recommendation for the required replacement of defibrillators for Ottawa-Carleton. It is our understanding that the existing units are continuing to have failures and pose a risk to the health of our community.

The replacement of the existing monitor / defibrillator is a critical issue due to their decreasing reliability. We are also aware that the Laerdal 3000 is inadequate as a diagnostic and reporting tool in the full ALS system which is mandated in Ottawa-Carleton, due to OPALS, and Regional Council's desire to continue with a full ALS system.

The quotation attached to the report fixes the price cited for a 60 (sixty) day period. We would appreciate confirmation that these prices will be honoured for at least the remainder of the 2000 calendar year, as stated in the proposal itself (#12 - Pricing). It would be preferable to maintain the quoted price through 2001, as there is a possibility that we will require additional machines in the future.

The Base Hospital Program's recommendation is supported by the Region. Regional Council approved funding it's share (50%) of the cost as per the quotation in the Regional ambulance capital transition budget established in December 1999.

Please confirm the Ministry of Health and Long-Term Care's concurrence that it will be funding it's share (50%) of the cost as per the quotation. Given the critical nature of the request, please provide your concurrence as soon as possible and advise when the purchase of these defibrillators will occur.

I look forward to hearing from you. Thank you for your assistance.

Yours truly,

Joanne Yelle-Weatherall
Director, Ambulance Health Services

JYW

cc: Dr. J. Maloney, Medical Director, Base Hospital Program of Ottawa-Carleton
Dr. R. Cushman, Medical Officer of Health, Region of Ottawa-Carleton
C.M. Beckstead, Chief Administrative Officer, Region of Ottawa-Carleton

ANNEX E

Region of Ottawa-Carleton
1655 Maple Grove Road
Kanata, ON K2V 1B7

Health Department
Ambulance Health Services
Tel. (613) 560-6053 x3557
Fax. (613) 591-1698

Région d'Ottawa-Carleton
1655, chemin Maple Grove
Kanata (ON) K2V 1B7

Service de la Santé
Services d'ambulance
Tél. (613) 560-6053 x3557
Télécopieur (613) 591-1698

27 March 2000

Mr. Blake Forsyth
Regional Manager
Emergency Health Services Branch, East Ontario
Ministry of Health and Long-Term Care
75 Spring Street, P.O. Box 790
Almonte, Ontario
K0A 1A0

BLAKE

Dear Mr. Forsyth:

The ever increasing number of defibrillator failures in Ottawa-Carleton has made it clear that the existing defibrillators need to be replaced immediately. The defibrillators have gone well beyond their expected life span and there is extensive documentation by Mr. Mark Cleland, Biomedical Department of the Ottawa Hospital on their failure rate.

As you know, the selection of the new defibrillator was made through a Base Hospital Committee with Ministry and Regional representation. Of the four companies that responded to the request for new defibrillators, Zoll Medical Corporation was selected by the Committee. The contract for 35 new defibrillators, in the amount of $876,754.40 will be awarded immediately to Zoll Medical Corporation. Paramedics will be trained in their use as soon as practical.

To solve the problem of defibrillator failure problem, the Region will now proceed with the purchase of the new equipment, and we fully anticipate the Ministry's contribution in this important effort to upgrade ambulance services in Ottawa-Carleton.

Sincerely,

Robert Cushman, MD, FRCPC
Medical Officer of Health

/hf

cc: Dr. J. Maloney, Medical Director, Base Hospital Program of Ottawa-Carleton
M. Cleland, Biomedical Engineering Technologist, General Campus, Ottawa Hospital
G. Brand, Director, Emergency Health Services Branch, MOH&LTC

M. Kardos Burton, Executive Director, Health Care Programs, MOH&LTC
J. King, Assistant Deputy Minister, Health Care Programs Division, MOH&LTC
C.M. Beckstead, Chief Administrative Officer, Region of Ottawa-Carleton
J. Yelle-Weatherall, Director, Ambulance Health Services, Region of Ottawa-Carleton

Ministry of Health and Long-Term Care
Ministère de la Santé et des Soins de longue durée

Ontario

Emergency Health Services Branch
75 Spring Street, Box 790
Almonte, ON K0A 1A0

Direction des services de santé d'urgence
75, rue Spring, C.P. 790
Almonte, ON K0A 1A0

Telephone\Téléphone: (613) 256-3070
Facsimile\Télécopier: (613) 256-4318

File: RMOC 187BH

April 10th, 2000

Ms. Joanne Yelle-Weatherall
Director
Land Ambulance Services
Regional Municipality of Ottawa-Carleton
495 Richmond Road, 7th Floor
Ottawa, ON K2A 4A4

Re: Defibrillator Replacement

Dear Ms. Yelle-Weatherall:

I am responding to your fax of March 10th, 2000 about the provision of defibrillator services in your area.

As you know, the Ministry of Health and Long-Term Care (MOHLTC) and the Upper Tier Municipalities (UTMs) are committed to a partnership approach to the provision of land ambulance services and this includes defibrillation services. Approved Base Hospitals, as agents of the MOHLTC, are responsible to participate in that partnership.

If the need for a defibrillator replacement, based on age, excessive maintenance costs etc. is demonstrated, then the costs of unit(s) that meet but do not exceed Ministry equipment standard are shared. If the standard is exceeded due to a desire by your Municipality to change the procedures associated with the use of defibrillators, then costs associated with these changes are borne fully by the Municipality. Also, you indicate that the Laerdal HS3000 QR is inadequate as a diagnostic tool in the A.L.S. system mandated by OPALS. This is not correct. The Medical Directors from all OPALS participating communities agreed that the HS3000 QR with a manual module would be the standard for OPALS. As I stated previously, if the Municipality wishes to exceed the standard, the costs associated with the change would be borne by the Municipality.

The Zoll M series Multi Pro Plus proposed by Ottawa-Carleton significantly exceeds the standards for the Ministry defibrillator specification. A Zoll M series monitor defibrillator similar to the Ministry specification has been calculated at a cost of $15,367/unit including all accessories, batteries and GST.

Therefore, the following calculations would apply:

a) 34 Zoll Defibrillator Monitor units
(adjusted equivalent to MOHLTC equipment standard)

34 x $15,367 x 50% = $261,239

b) Minus 50% of trade in value of
32 Laerdal 3000QR @ $1,788/unit = 32 x $1,788 x 50% = ($28,608)

c) 1 free Zoll DM unit on closure of transaction

Total 35 units = **$232,631**
(Ministry share)

Please provide us with your preference regarding the distribution of these funds.

Trust that you find this satisfactory and please feel free to call.

Yours truly,

R. Blake Forsyth
Regional Manager
East Ontario

RBF/gm

cc Dr. J. Maloney, Medical Director, Ottawa Base Hospital
Dr. R. Cushman, Medical Officer of Health, Ottawa-Carleton Health Department
C.M. Beckstead, C.A.O., Regional Municipality of Ottawa-Carleton
G. Brand Director Emergency Health Srevices MOHLTC
M. Bates Senior Manager Patient Care Services MOHLTC
M. Kardos Burton Executive Director Health Care Programs MOHLTC
J. King Assistant Deputy Minister, Health Care Programs Division MOHLTC

The Ottawa Hospital
Base Hospital Program
Ottawa-Carleton
General Campus, SD Level
501 Smyth Road
Ottawa, Ontario K1H 8L6

DATE: January 10, 2000
revised
TERMS: Net 30 Days

FOB: Burlington, MA

ATT: Mr. Andrew Orchard
FAX: (613) 737-8008

ITEM	PART/MODEL NUMBER	DESCRIPTION	QTY.	UNIT PRICE	DISC. PRICE	TOTAL PRICE
1	4142022180018301	M Series AED/Manual Defibrillator with ZOLL Rectilinear Biphasic Waveform, DC Power, Multiple Application Printer & Summary Report, SPO2 with reusable sensor and 8' cable, Code Markers, Noninvasive Pacing and ZOLL 12-Lead with 1-step cable	36	$31,588.00	$20,682.56	$703,210.44 *
	MULTI-PRO PLUS	Includes: High Contrast Display, 3-lead patient cable with integral lead wires, universal cable for ZOLL Multi-Function Electrodes, two re-chargeable lead acid battery, ac mains power cord, one package of recorder paper, integral diagnostic ECG frequency response, PC card slots and operator's manual. Standard 1 Year BMS Warranty.				
2	8000-0034-01	Xtreme Pack II Carry Case w/ Rear Pouch & Side Pockets w/ Modem Extension Cable	35	$247.00	$247.00	$8,645.00 *
3	8650-0003-01	Replacement Rear Pouch for Xtreme Pack II	35	$124.00	No Charge	No Charge *
4	8350-0002-01	ZOLL Base PowerCharger 4x4 Battery Charger/Tester with Auto Test. Includes: Three Batteries and One Operator's Guide	22	$2,458.00	$1,843.50	$40,557.00 *
5	8204-0102-01	Smart Battery (In lieu of standard at time of purchase)	146	$75.00	$56.25	$8,325.00 *
6	8004-0102-01	Smart Battery Complete	12	$291.00	$203.00	$2,436.00 *
7	8000-1515	Playback System, Package 2 Package includes: Playback Software, Cable and Card Reader	1	$863.00	$647.31	$647.31 *
8	NPN	16 meg PCMCIA Data Cards	35	$653.00	$489.75	$17,141.25 *
9	NPN	16 meg PCMCIA Data Cards	40	$652.00	No Charge	No Charge
		Stand Alone NIBP Devices (To be delivered & supported by NIBP Manufacturer).	30	$2,350.00	$2,350.00	$70,500.00
		Laptop Computer for Field Download	2	$2,250.00	$2,250.00	$4,500.00
		Desktop Computer for Data Review	1	$1,500.00	$1,500.00	$1,500.00
10	8012-0206	12-Lead Simulator	2	$1,443.00	No Charge	No Charge *
11	8000-1510	Training Cable	2	$73.00	No Charge	No Charge *
12	8900-5005	Training Electrodes (5 sets/case)	2	$108.00	No Charge	No Charge *
13	8000-0025	3 Lead Patient Cable	5	$126.00	No Charge	No Charge *
14	8650-0201-01	Configuration Manual	2		No Charge	No Charge *
15	8650-0073	M Series Inservice Video	12	$36.00	No Charge	No Charge *
16		M Series Service Manual	2		No Charge	No Charge *
17	8650-0200-01	Operator Manual	250		No Charge	No Charge *
18	9305-0520-01	Short Operating Guide	250		No Charge	No Charge *
19	3000-1010-01	M Series External Paddle Assembly (Apex/Stemum)	35	$788.00	$542.64	$18,992.40 *
		*Reflects Discount Pricing				
		TRADE-IN ALLOWANCE				
20	7300-0155	Laerdal 3000QR ** Trade-in value valid if all units purchased are in good operational and cosmetic condition and include all standard accessories such as paddles, cables, etc.	32	($1,788.00)		
		ALL PRICES ARE QUOTED IN CANADIAN DOLLARS			TOTAL	$876,754.45

WE PROPOSE TO FURNISH THE ITEMS LISTED ABOVE, SUBJECT TO CONDITIONS SET FORTH ON THE REVERSE SIDE HEREOF, AND THE WRITTEN ACCEPTANCE OF THIS QUOTATION.

1. DELIVERY WILL BE MADE AFTER JUNE 2000.
2. PRICES WILL BE F.O.B. BURLINGTON, MA.
3. WARRANTY PERIOD (See above and reverse side).
4. LIST PRICES QUOTED ARE FIRM FOR 60 DAYS.

Neil Johnston
Territory Manager