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National Marrow  
Donor Program@

National Coordinating Center  
3433 Broadway Street N.E.  
Suite 500  
Minneapolis, MN 55413  
612-627-5800  
1-800-526-7809  
FAX: 612-627-8125

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A collaborative effort of the:

**American Association  
of Blood Banks  
American Red Cross  
America's Blood Centers**

With federal funding from:  
Health Resources and Services  
Administration and  
Naval Medical Research and  
Development Command

December 22, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fisher's Lane, Room 1061  
Rockville, MD 20852

Dear Sir or Madam:

Enclosed please find the National Marrow Donor@ comments requested by the FDA on the "Suitability Determination for Donors of Human Cellular and Tissue-Based Products" [Docket No. 97N-484S].

Should you have any additional questions in regard to these comments, please feel free to contact me at 6 12-362-3425.

Sincerely,

DennisL. Confer  
Chief Medical Officer

Enclosure

copy: Fran Rabe  
Regulatory File

97N 484S

C215

**Suitability Determination for Donors of Human Cellular and Tissue-Base Products**

**Docket No. 97N-484S**

**National Marrow Donor Program@ Comments**

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The National Marrow Donor Program® (NMDP) urges the agency to consider the method of implementation of the final "Suitability Determination for Donors of Human Cellular and Tissue-Based Products", new part 1271.

As the agency is aware, currently cord blood does not fall under the auspice of the Final Tissue Rule, 21 CFR part 1270. Therefore, cord blood bank's current inventories were not collected under either the Tissue Interim Rule of December 14 1993 or the Final Tissue Rule effective January 26, 1998.

The NMDP urges that implementation of the new part 1271 takes into consideration the availability of these previously collected cord blood units when determining the method for implementation of the new tissue regulations. It is imperative that the availability of cord blood units for transplantation into critically ill patients, normally the patient's last and only option for treatment, is not jeopardized. The NMDP suggests that cord blood units, which have been collected under an IND prior to the date of effectivity of the new final "Human Tissue Intended for Transplantation", would still be acceptable for distribution and transplantation after the new part 1271 becomes effective.

**D. Donor Screening (Proposed 1271.75)**

**1. Physical Requirements**

Issue for Comment: "Physical examination of the living donor is required.

Request clarification in regard to the purpose and extent of the physical examination of the **living donor**, specifically the cord blood donor.

The current "Human Tissue Intended for Transplantation" [Docket No. 93N-0453], 1270.3 (n) defines a physical assessment as "a limited autopsy or recent antemortem or postmortem physical examination of the donor to assess for any signs of HIV and hepatitis infection or signs suggestive of any risk factor for such infections. ...". (This is clearly intended for the cadaver donor and does not address the physical evidence pertaining to the physical exam of the **living** donor.)

Also, the Guidance for Industry; "Screening and Testing of Donors of Human Tissue Intended for Transplantation", July 1997, addresses examination of the cadaver donor and does not address the physical evidence pertaining to the physical exam of the **living** donor. See the following excerpt pertaining to the physical exam:

"Physical Evidence"

"Physical assessment of all tissue donors aids in donor suitability determinations because it provides an additional level of assessment for high risk behaviors or clinical evidence

of infection with HIV or hepatitis. 21 CFR 1270 defines a physical assessment as a limited autopsy or recent antemortem or postmortem physical examination of the donor to assess for any evidence of high risk behavior and signs of HIV and hepatitis infection”.

NMDP suggests a modified version of the “limited physical examination”, as defined by the American Association of Blood Banks, Technical Manual 13<sup>th</sup> Edition. This modified version of a limited physical examination should be sufficient in the cord blood donor to provide additional assurance that the donor is healthy and free of current or past drug use. The cord blood donor limited physical examination should include:

- 1) Review of general appearance
  - 2) Skin lesions on the arms indicative of drug use.
  - 3) Arm skin with boils, purulent wounds, or severe infection, purplish-red or hemorrhagic nodules or indurated plaques suggestive of Kaposi’s sarcoma.
  - 4) Temperature
- 

## **E. Donor Testing**

### **1. General Requirements 1271.80(b)**

Issue for Comment: Timing of the collection of the cord blood donor blood sample for testing.

NMDP suggests that the cord blood sample from the biological mother may be collected up to 48 hours prior to the time of recovery of the cord blood unit or within 7 days after recovery.

Collection of the blood sample for the cord blood donor within 48 hours after donation of the cord blood unit may be difficult to obtain from the mother due to her release from the hospital and may therefore result in the discard of the cord blood unit as a result of inability to meet this requirement. Allowing up to 7 days to collect the sample would provide the necessary flexibility, and would not jeopardize the integrity of the test results in any way. In fact, later collection of the test sample would further close any potential “infectivity window” of the donor. The National Marrow Donor Program standard 8.2410 permits collection of the blood sample for infectious disease testing prior to or within 7 days after collection of the cord blood unit<sup>1</sup>.

### **1. General Requirements 1271.80(b)**

Issue for Comment: Timing of the collection of the peripheral blood donor blood sample for testing.

The NMDP agrees that in certain circumstances it is necessary to perform donor testing prior to the recovery of cells or tissue. The NMDP believes that an additional justification for such prior testing occurs when the recipient of cells or tissue must receive intensive therapy prior to implantation, transplantation, infusion or transfer. In this regard, the proposed 7-day time frame is not adequate. In the case of hematopoietic stem cell transplant recipients, preparative regimens consisting of chemotherapy alone or chemotherapy and radiation are often initiated 7 – 10 days prior to the stem cell infusion. Furthermore, extensive scheduling is required to arrange an unrelated donor stem cell transplant. Donor arrangements include travel reservations, time off from work, scheduling of collection facilities, product transportation and others. Transplant hospitals must also anticipate and schedule recipients on the basis of bed availability, radiation therapy schedules, etc. These and other logistical considerations necessitate that donor testing occurs well in advance of initiating the recipient's preparative therapy. NMDP Standards specify that donor testing for communicable disease agents and diseases must be performed within 30 days prior to the scheduled collection. Testing of the first product at collection is also required. The NMDP believes these procedures have a proven safety record.

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## **E. Donor Testing**

### **2. Specific Requirements (Proposed 1271.85)**

Issue for Comment: Proposed 1271.85 (d) would require retesting of the donor for infectious disease markers at least 6 months after the date of donation of reproductive cells or tissue that can reliably be stored.

With respect to placental/umbilical cord blood, the NMDP objects to the concept that cells and tissues that can be reliably preserved are held to a higher standard than those which can not. This requirement is not imposed upon stored blood components, such as fresh frozen plasma. This requirement for retesting would place an extraordinary financial burden on the placental/cord blood industry that has not been considered by the Agency in its impact analysis. The NMDP has estimated that the utilization, i.e., transplantation, rate for stored placental/umbilical cord blood units is below 5%. Why should these products, which are infrequently utilized – in comparison for example to packed RBC units - and targeted exclusively for a select, high-risk proportion of the population, i.e., hematopoietic stem cell transplant recipients, be held arbitrarily to a higher, burdensome standard? Finally, the NMDP believes the requirement for retesting discriminates arbitrarily and unfairly against low-income donors, who by virtue of their socioeconomic status are less likely to be available for retesting at a future date<sup>2</sup>. We urge that retesting of the placental/umbilical cord blood donor or mother not be recommended or required.

References

1. National Marrow Donor Program® Standards, 17<sup>th</sup> Edition.
2. Guidry J, Aday L, Zhang D, Winn R. Transportation as a Barrier to Cancer Treatment. *Cancer Practice* 1997;5:361-366.

# **National Marrow Donor Program®**

## **Standards**

### **17<sup>th</sup> Edition**

**Effective September 1, 1999**

#### **Notice and Disclaimer NMDP Standards**

These standards set forth only the basic guidelines for programs working through the NMDP to facilitate hematopoietic progenitor cell transplants. These standards do not set forth all that may be required of a facility or individual to conform to federal or state laws or regulations (or non-U.S. equivalent) or the standard of care prevailing in the relevant community. Each facility and individual must determine and follow any additional laws, regulations, practices and procedures that apply in their particular community. The NMDP disclaims all representations or warranties, expressed or implied, that compliance with the NMDP Standards will fulfill the requirements of all applicable federal or state laws and regulations (or their non-U.S. equivalent) or the standard of care prevailing in the relevant community.

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**Affiliated Center**

Apheresis center that is not an NMDP approved facility but is capable of meeting all the collection requirements set forth in the NMDP protocol for collection of blood cells by apheresis (Applicable to Apheresis Center designation only).

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**American Society of Histocompatibility and immunogenetics (ASHI)**

Professional organization for histocompatibility and immunogenetics experts and an accrediting agency within the United States for histocompatibility testing laboratories.

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**Apheresis Center**

Facility approved by the NMDP for the collection of blood progenitor cells by apheresis from NMDP volunteer donors.

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**Apheresis Collection:****Stimulated**

HPC collection using apheresis techniques after the donor has received growth factor.

**Unstimulated**

Leukocyte collection using apheresis techniques without the administration of growth factor.

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**Clinical Laboratory Improvement Act (CLIA)**

A federal statute and a series of federal rules and regulations for clinical laboratories initially published in the Federal Register in 1988 and subsequently modified.

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**Clinical Practice Guideline**

Standardized disease-specific treatment plan used in lieu of a research protocol when use of an unrelated donor transplant is considered standard of care.

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**Collection Center**

Hospital based facility that is approved by the NMDP to collect marrow from unrelated volunteer donors.

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**Cord Blood Bank**

Facility in which hematopoietic progenitor cells from the placental and umbilical cord blood vessels are processed, cryopreserved, and/or stored.

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2.4300 Center shall use trained phlebotomists.

2.5000 Policies and Procedures

2.5 100 Center shall maintain **written** standard operating procedures (SOPs) and policies for the recruitment and management of volunteer donors.

2.6000 Applicant Center

2.6 100 Applicant shall meet all criteria for participating Donor Centers.

2.6200 Applicant shall demonstrate that its donor management abilities, recruitment strategies, and its geographic location or population demographics warrant the establishment of a new center.

2.6300 Applicant shall have an HLA-A.B typed file of at least 1000 persons meeting NMDP donor eligibility that could be approached as marrow donors, or be able to show community support for funding the HLA-A.B typing of at least 500 new marrow donors.

**2.6100** Applicant organization established to recruit donors for a specific patient shall not be eligible for consideration as a Donor Center until the needs of that patient have been resolved.

**3.000 Criteria for Participating Donor Recruitment Groups**

2.1000 Group Characteristics

3.1100 Group shall have permanent or preliminary IRS designation as a 50 1 (c) ( 3 ) tax exempt non-profit organization.

3.1200 Group shall have a Board of Directors with at least five members including individuals with outreach to the targeted group(s) sought for recruitment.

3.1400 Group shall recruit new donors in accordance with priorities of the NMDP.

3.1500 Group shall have a **written** collaborative agreement with each NMDP Donor Center that has agreed to accept the recruited HLA typed donors.

3.1600 Groups shall only recruit donors for inclusion in the NMDP.

# NATIONAL MARROW DONOR PROGRAM® STANDARDS

## **1 .0000      General**

- 1.1000      Participating programs shall comply with NMDP standards, policies and procedures that include but are not limited to:
  - 1.1100      Completion of all applicable NMDP data forms.
  - 1.1300      Participation in the NMDP Continuous Process Improvement (CPI) program.
  - 1.1400      Provision of annual documentation that NMDP participation and CPI criteria are met.
- 1.2000      Director of a participating program shall be responsible for compliance with these Standards.
- 1.3000      Deviations from these Standards shall be approved according to NMDP policies and procedures.
- 1.4000      Significant changes in personnel, facility or support services shall be reported promptly to the National Coordinating Center.
- 1.5000      Participating programs shall establish a system of strict confidentiality of records to protect the privacy of potential donors, donors and patients.
- 1.6000      Clinical research protocols shall be approved by an Institutional Review Board.

## **2.0000      Criteria for Participating Donor Centers**

- 2.1000      Facility Characteristics
  - 3.1100      Center shall have demonstrated experience in the recruitment and management of blood, apheresis or marrow donors, including education, counseling, confidentiality issues and medical screening.
  - 2.1200      Center shall have adequate resources to support its donor recruitment and management activities.
  - 2.1300      Center shall have a designated site for donor management activities, a private space for donor counseling sessions and locked file cabinets for record storage.
  - 2.1400      Center shall have an information management system and merge data according to NMDP requirements.
  - 2.1500      Center shall have collaborative agreement(s) with participating marrow Collection Center(s).

**4.0000 Criteria for Participating Cord Blood Banks**

4.1000 Facility Characteristics

- 4.1100 Bank shall have demonstrated experience in the recruitment and management of cord blood collections, including education, counseling, confidentiality issues and medical screening.
- 4.1200 Bank shall have adequate resources to support its recruitment and management activities.
- 4.1300 Bank shall have adequate and secure facilities for processing, storing and retrieving cord blood units and samples.
- 4.1300 Bank shall have a designated site for management activities and locked file cabinets for record storage.
- 4.1200 Bank shall have an information management system and merge data according to NMDP requirements.
- 4.1600 Bank shall have collaborative agreements with facilities collecting cord blood units.

**4.2000 Medical Director**

- 4.2100 Bank shall have a medical director who is a licensed physician.
- 4.2200 Bank medical director shall be responsible for reviewing the medical evaluation of the donor and biologic mother for evidence of disease transmissible by transfusion or transplantation.
- 4.2300** Bank medical director shall be responsible for the protocols pertaining to: recruitment, informed consent, evaluation and follow-up of the potential donor, and for the collection, transportation, manipulation, cryopreservation and storage of the unit.

**4.5300** Bank shall have written policies and procedures for the release and issue of cord blood units and for the return to inventory of unused cryopreserved units.

4.6000 Applicant Bank

4.6100 Applicant shall meet all criteria for participating Cord Blood Banks.

3.6200 Applicant shall have stored a minimum of 100 cryopreserved cord blood units that each meet NMDP criteria.

**5.0000 Criteria for Participating Marrow Collection Centers**

5.1000 Facility Characteristics

5.1100 Center shall be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or non-US equivalent.

**5.1200** Center shall have an experienced team that has collected marrow at least four times in the past year at the center.

5.1300 Center shall have adequate resources to support its collection and management activities.

5.1300 Center shall have a designated site for management of collection activities.

**5.1500** Center shall have collaborative agreement(s) with participating Donor Center(s).

**5 2000** Medical Director

**5.2100** Center shall have a medical director who is a licensed physician.

5.2200 Center medical director shall be responsible for reviewing the medical evaluation of the donor for risks of donation and evidence of disease transmissible by transfusion or transplantation.

**5.3000** Personnel

5.3100 'Collection Center physician performing the marrow collection shall have performed at least 12 prior collections of marrow for transplantation with at least four collections in the previous three years. Any person assisting in the marrow aspiration (physician,

- 5.5300** Center shall verify that the donor has autologous red cell units. appropriate to the anticipated volume of marrow to be collected. available prior to the marrow collection.
- 5.5400** Center physician responsible for the collection shall be present for the duration of the marrow collection.
- 5.5500** Center physician shall be responsible for determining that the donor's health is appropriate for discharge.
- 5.6000** Applicant Center
  - 5.6100** Applicant shall meet all criteria for participating marrow Collection Centers.
  - 5.6200** Applicant shall provide documentation of need from an existing Donor Center.

**6.0000 Criteria for Participating Apheresis Collection Centers**

- 6.1000** Facility Characteristics
  - 6.1100** Center shall be an institution that is appropriately licensed and/or registered with the Food and Drug Administration or be in compliance with the appropriate non-US equivalent laws and regulations.
  - 6.1200** Center shall have documented experience in the collection of cellular components by apheresis. and shall have performed at least three collections of blood mononuclear cells by apheresis in the past year.
  - 6.1300** Center shall have adequate resources to support its collection and management activities.
  - 6.1300** Center shall have a designated site for management of collection activities.
  - 6.1500** Center shall have collaborative agreement(s) with participating Donor Center(s).
- 6.2000** Medical Director
  - 6.2100** Center shall have a medical director who is a licensed physician qualified by training and experience to supervise mononuclear cell collections.

6.5000 Policies and Procedures

- 6.5100 Center shall maintain written SOPs and policies for the collection, testing, storage, labeling, and transport of blood components and for the maintenance of apheresis equipment.
- 6.5300 Responsible physician shall perform and/or review a complete medical evaluation to determine if the donor is an acceptable candidate for apheresis donation.
- 6.5300 Physician experienced in growth-factor administration shall be available throughout growth factor administration and follow up.
- 6.5400 Physician shall be available on-site for the duration of each collection procedure and for follow-up as needed.

6.6000 Applicant Center

- 6.6100 Applicant shall meet all criteria for participating Apheresis Centers..
- 6.6200 Applicant that is not part of a Donor Center shall provide documentation of need from an existing Donor Center.

**7.0000 Criteria for Participating Transplant Centers**

7.1000 Facility Characteristics

- 7.1100 Center shall be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or non-US equivalent.
- 7.1200 Center shall have an experienced team that has performed at least 10 allogeneic transplants per year.
- 7.1300 Center shall have a designated inpatient unit that minimizes airborne contamination.
- 7.1300 Center shall have a designated area for outpatient evaluation and treatment that reduces the risk of transmission of infectious agents.
- 7.1500 Center with geographically non-contiguous patient care units shall demonstrate functional unity through shared mechanisms such as medical director, coordinator, standard operating policies and procedures, data management, cell processing laboratory, and training of support personnel.

7.3500 Center shall have a patient advocate who is familiar with the center's program and issues of unrelated donor hematopoietic cell transplantation. but is not a member of the transplant team.

7.4000 Support Services

7.4100 Center shall use the following facilities for NMDP activities:

7.4110 HLA typing laboratory(ies) accredited by the American Society for Histocompatibility and Immunogenetics (ASHI) or the European Foundation for Immunogenetics (EFI) for techniques required by NMDP.

7.4120 Laboratory(ies) certified by CLIA (or non-US equivalent) for all clinical laboratory tests required by NMDP.

7.4200 Center shall use a transfusion service providing 24-hour blood component support for transplant patients. including irradiated blood components and components suitable for CMV-negative recipients.

7.4300 Center shall use an experienced hematopoietic progenitor cell processing laboratory.

7.4100 Center shall have experienced physicians who provide consultative services in at least the following disciplines: surgery, pulmonary medicine, intensive care, gastroenterology, nephrology, infectious diseases, cardiology, pathology, psychiatry, and, if applicable, radiation therapy.

7.1500 Center shall have sufficient staff from at least the following services: pharmacy, dentistry, dietary, social services and physical therapy.

7.5000 Policies and Procedures

7.5100 Center shall maintain written policies and/or SOPs to address at least the following:

7.5110 Donor and recipient selection

7.5120 Financial approval

7.5130 Recipient evaluations

**7.6000** Applicant Center

7.6100 Applicant shall meet all criteria for participating Transplant Centers.

**7.6300** Applicant facility and medical team, including medical director and at least one other physician experienced in allogeneic transplantation shall have been performing transplantation at that site for at least one year.

**7.6300** Applicant shall have performed at least 10 allogeneic transplants per year during the previous 24 months or 20 allogeneic transplants in the last 12 months.

**7.7000** Patient Advocacy

7.7100 Center shall communicate appropriate information about the progress of a search to patients, families and physicians.

**7.7200** If a compatible donor is not found, according to the criteria of the transplant center, the patient shall be informed of other options, including:

7.7210 Referral to approved transplant centers whose criteria for unrelated transplant are different.

**7.7220** Repeated NMDP search results as more donors are added.

**7.7230** Search results of other registries.

**8.0000** Recruitment of HPC Donors

8.1000 Marrow or Apheresis Donor

8.1100 Donor shall be between the ages of 18 and 60.

8.1300 Donor shall appear to be in good health.

8.1300 Donor shall provide a medical history and acknowledge in writing that the history is accurate.

8.1300 Pertinent donor medical history shall be evaluated for acceptance or deferral according to the current NMDP medical eligibility chart and criteria of local Donor Center medical director.

**8.2230** Biologic mother shall acknowledge in writing that she has read and understood the educational material, has been given ample opportunity to ask questions and has had those questions answered satisfactorily.

8.2300 Biologic mother shall not be coerced to donate cord blood.

**8.2400** Cord Bank shall test a blood sample from the biological mother of cord blood donor for infectious diseases as defined for marrow or apheresis donor.

8.2310 Blood sample from biological mother of cord blood donor used for infectious disease testing shall be obtained within 7 days prior to or within 7 days after HPC collection.

**8.2320** Cord Bank shall inform, counsel and document counseling of biological mother regarding any abnormal findings.

**8.2500** Medical director or designee shall evaluate medical history and testing results prior to listing the cord blood unit with the NMDP.

**9.0000 Donation Process**

9.1000 Additional Testing/Information

9.1100 Patient Directed DR Typing

9.1110 If a stored sample is used for DR testing, the potential donor should be informed that DR typing is in progress and given the opportunity to continue or withdraw.

9.1120 If a new blood sample is required, potential donor shall sign a consent form agreeing to provide a blood sample for additional testing.

9.1200 Confirmatory Testing

9.1210 Donor Center shall provide potential donor with educational materials regarding the risks of infectious disease transmission by transplantation.

9.1220 Donor shall sign a consent form each time a blood sample is obtained for additional testing.

9.1261 Donors with a confirmed positive test for HBsAg or HCV should not be used.

9.1262 Donors with a confirmed positive test for anti-HIV 1/2 or HIV-1 antigen shall not be used.

9.1300 Repeat HLA Typing

9.1310 Transplant Center shall repeat HLA-A, B and DR typing of any donor selected for marrow donation.

9.1320 Results of the confirmatory HLA typing performed by the Transplant Center shall be sent to the NMDP.

9.1330 Transplant Center shall make decisions on donor acceptability as soon as possible so that donors inappropriate for that recipient may be returned to the active search files.

9.2000 Information Session

9.2100 Information as required by the NMDP shall be provided to the selected potential marrow or apheresis donor before consent is obtained.

9.2200 Donor should be encouraged to include spouse, family members or friends in the information session.

9.2300 Prospective marrow or apheresis donor shall be informed of at least the following:

9.3310 Right to withdraw at anytime, but extreme risk of death for the recipient if the donation is not completed once the preparative regimen is begun.

9.2320 Opportunity to discuss his/her decision with a donor advocate.

9.2330 Further tests and examinations to be done.

9.2310 Magnitude of the time commitment involved in the donation process.

- 9.3200 Medical history
  - 9.3210 Donor Center shall obtain from the donor a medical history that meets NMDP requirements.
  - 9.3230 Medical history indicative of disease or risk of infectious disease shall be evaluated by a physician to determine the donor's eligibility.
- 9.3300 Medical examination
  - 9.3310 Examining physician
    - 9.3311 Examining physician shall be a licensed and is responsible for protecting the safety of the donor and for delineating conditions in the donor that may be transmissible by transfusion or transplantation.
    - 9.3312 Examining physician shall be designated by medical director of Donor or Apheresis Center.
    - 9.3313 Examining physician shall not be part of the transplant team of the center performing the transplant.
  - 9.3320 Examining physician shall perform and/or evaluate a complete medical history and physical examination to include special notation of the following:
    - 9.3321 Pregnancy assessment.
    - 9.3322 Deferral from blood donation.
    - 9.3323 Contraindications to marrow or apheresis donation.
    - 9.3324 Findings that would increase the anesthesia risk for the prospective donor.
  - 9.3330 Examining physician shall obtain and evaluate the results of the following tests:
    - 9.3331 Complete blood count

9.4000 Prospective Donors with Abnormal Findings

- 9.4100 Donor Center medical director or designee shall report to the donor any abnormal findings discovered during donor evaluation.
- 9.4110 Donor shall be counseled about the potential impact of the abnormality.
- 9.4120 Written documentation of counseling regarding abnormal finding shall be maintained at the Donor Center.
- 9.4130 Donor has the right to decline donation based on the abnormal findings and keep the reason(s) confidential.
- 9.1200 Abnormal finding that may increase risk to the donor.
- 9.4210 Donor Center medical director and Collection Center medical director (or examining physician) shall determine whether an abnormal finding constitutes unacceptable risk to the donor.
- 9.3220 If the donor agrees to donate, any abnormal finding that may increase risk in the prospective donor shall be reported by the Donor Center to the NMDP.
- 9.4300 Abnormal finding that may increase risk to the recipient.
- 9.4310 Transplant Center medical director shall determine whether hematopoietic progenitor cells from a donor with an abnormal finding poses unacceptable risk to the recipient.
- 9.4320 Decision to use hematopoietic progenitor cells from a donor with an abnormal finding that may increase risk to the recipient shall be communicated by the Transplant Center, in writing, to the NMDP.
- 9.4330 Abnormal finding that may increase recipient risk shall be reported to the recipient, who shall be appropriately counseled as to the potential impact of the abnormality.
- 9.4331 Written documentation of counseling shall be maintained at the Transplant Center.

9.5313 Total nucleated cell count.

9.5314 If requested, the total number of CD 34 positive cells to be obtained.

9.6000 Pre-Collection Donor Blood Samples

9.6100 Pre-collection donor blood samples in excess of those required for autologous units and samples needed to assess the physical well being of the donor should be:

9.6110 Limited to a maximum of 100 mL in the month prior to marrow donation.

9.6120 Obtained more than 10 days prior to marrow collection.

9.7000 Subsequent Donor Contacts

9.7100 Following the donation, Donor Center shall evaluate the well-being of the donor in the following manner:

9.7110 Telephone call or direct conversation with the donor shall be made within 48 hours of the donation.

9.7120 Contact with the donor shall be repeated between five and seven days after donation.

9.7130 If the donor has any unusual complaints, donor shall be referred to an appropriate source of medical care.

9.7110 Contacts with donor shall continue until the donor is free of complaints related to HPC the collection.

9.7200 Subsequent demands on the donor

9.7210 Donor shall be asked to provide blood components for the recipient after the transplant only for NMDP approved indications.

9.7230 Donor may be asked to provide an additional marrow or apheresis collection, for the same recipient following NMDP Second Donation Request Policy.

9.7230 Reuse of the same donor for a different recipient at a later time is not recommended unless no other equally

- 10.1500 Marrow should contain the target number of nucleated cells specified by the marrow prescription.
- 10.1510 Collection Center shall count the nucleated cells collected.
- 10.1600 Marrow volume shall not exceed 20 ml/kg donor body weight and should not exceed 1500 ml.
- 10.1610 Marrow volume should not be so large as to necessitate transfusion of allogeneic blood.
- 10.1700 Marrow shall be filtered during collection using sterile filters made of materials that do not deplete leukocytes.
- 10.1800 Marrow shall be divided into approximately equal portions and packaged in at least two sterile, closed, labeled blood bags approved for HPC storage, each with ports that can be entered aseptically.
- 10.2000 Apheresis Collection (stimulated and unstimulated)
- 10.2100 Apheresis collection shall be performed using an instrument and software designed for mononuclear cell collection.
- 10.2200 Apheresis collection shall be performed using ACD anticoagulant in a volume sufficient to prevent extracorporeal clotting.
- 10.2300 Total volume of blood processed per procedure shall not exceed 20 liters.
- 10.2400 After collection, Apheresis Center shall not add anticoagulants, further process or freeze collection without the direct consent of the Transplant Center and approval of the NMDP.
- 10.2410 Any additions or further processing shall only be performed by Transplant Center or laboratory designated by the Transplant Center.
- 10.3500 Target parameters of apheresis collection shall be specified by prescription.
- 10.2510 Apheresis Center shall obtain count of nucleated cells collected.
- 10.2600 Growth factor stimulated HPC collection

10.5300 Second individual shall verify each item recorded on the label and accompanying documents for accuracy.

10.5310 Identity of both individuals verifying information shall be documented.

10.6000 Transportation

10.6100 Each collection bag shall be placed in an outer bag which is sealed to prevent leakage.

10.6300 Collection bag(s) shall be enclosed in a rigid container with temperature insulating properties.

10.6300 Transportation conditions.

10.6310 Non-cryopreserved products shall be transported at the temperature specified by the Transplant Center or NMDP.

10.6311 Product shall be insulated from direct contact with wet ice or frozen gel packs.

10.6312 Dry ice shall not be used.

10.6320 Cryopreserved HPC collections (storage temperature below -80°C) shall be shipped in a liquid nitrogen "dry shipper" that contains adequate adsorbed liquid nitrogen to maintain temperature at least 48 hours beyond the expected arrival time at the receiving facility.

10.6321 Dry ice shall not be used unless this maintains the indicated storage temperature of the component being shipped.

10.6100 Donor Center shall arrange HPC transportation by a means which minimizes transit time.

10.6110 Donor Center shall evaluate alternative means of transportation in case primary means fails.

10.6500 If intended recipient has received myeloablative therapy the HPC collection shall be hand carried by a suitably informed courier in the passenger compartment of the transport vehicle.

10.6510 Cryopreserved collection shall be transported in the passenger compartment if permitted by the commercial carrier.

prior to listing the cord blood unit with the NMDP.

10.3400 Cord blood HPC units shall have at least one and should have at least two cryopreserved aliquots available for additional testing.

10.4000 Marrow or Apheresis Processing

10.4100 Collection Center shall not add anything, process or freeze collection except as requested by the Transplant Center and approved by the NMDP.

10.3200 Collection Center shall count the number of nucleated cells in the product.

10.4300 Transplant Center shall perform the following testing:

10.1310 Repeat ABO grouping and Rh typing of either blood or marrow obtained from the donor at the time of collection.

10.4320 Fungal and aerobic bacterial cultures.

10.3321 These cultures are not required for unmanipulated, unstimulated leukapheresis products.

10.4330 Stem cell quantitation by culture and/or surface phenotype if product is intended for engraftment.

10.4100 Marrow collection should be infused within 24 hours and apheresis collection should be infused within 48 hours of collection.

10.4410 Aliquots of marrow or apheresis HPC collection that are cryopreserved may be infused at a later date.

10.5000 Labeling and Documentation

10.5 100 Label shall contain at least the following:

10.1110 Product name

10.5 111 If marrow collection “ HUMAN HEMATOPOIETIC PROGENITOR CELLS. MARROW.”

11.5200 Copies of records pertaining to transferred donors who did not donate may be discarded by the transferring center after three years.

11.6000 Retention of Records – Closing Centers.

11.6100 Any center that ceases affiliation with the Program shall make provisions for maintenance or transfer of records to a facility designated by the closing center and approved by the NMDP.

- 11.2350 All modifications to the system shall be authorized and documented.
- 11.2400 All centers shall document the following:
  - 11.2410 Installation and upgrades of the system.
  - 11.2420 Training and continuing competency of personnel.
  - 11.2430 Policies and procedures for system maintenance and operations.
  - 11.2440 Ongoing backup procedures.
  - 11.2450 Documented and tested procedures for data restoration.
  - 11.2460 Offsite rotational storage of electronic data records.
- 11.3500 Computer records shall be protected to enable their accurate and ready retrieval throughout the period of required record retention.
- 11.2600 Center shall have an alternative system that permits continuous operation in the event that computerized data are not available.
- 11.3000 Retention of Records - Indefinite
  - 11.3100 Donor Records
    - 11.3110 Consent documents for all stases of the search process,
    - 11.3120 All health history screenings including infectious disease testing.
      - 11.5121 Reasons for permanent or temporary deferral.
    - 11.3133 Records documenting abnormal findings and the notification/counseling of the relevant parties.
  - 11.3130 ,411 records pertaining to any donor who donates marrow, cord blood, or peripheral blood progenitor cells.
    - 11.3131 Records of adverse reactions and post donation complications and recovery.

Jeffrey J. Guidry, PhD  
Lu Ann Aday, PhD  
Dong Zhang, MS  
Rodger J. Winn, MD

# Transportation as a Barrier to Cancer Treatment

**PURPOSE:** Patients with cancer must overcome many psychological, social, and economic barriers to obtain needed treatment. Because of the need for repeated visits for cancer treatment on either an outpatient or an inpatient basis, one of the major issues that patients with cancer must confront is that of arranging for transportation to care.

**METHODS:** This study compares the distance and mode of transportation to radiotherapy and chemotherapy and perceptions of transportation as a barrier to care among white, black, and Hispanic cancer patients receiving treatment from a consortium of cancer treatment facilities in Texas. A mail questionnaire was developed to assess the perceived barriers to cancer treatment for patients who had been diagnosed clinically with breast, colon, cervical, or prostate cancer, or lymphoma between 1989 and 1993. A total of 910 surveys were mailed to prospective participants. Of the surveys mailed, 593 were returned, yielding a 65.2% response rate. By race, the respondents included whites (42%), blacks (40%), Hispanics (15%), and Asian-Pacific Islanders (3%). Two respondents were 17 years of age; the remaining respondents were 18 years or older.

**RESULTS:** This study shows that some patients may forgo needed treatment because of problems with transportation. This was perceived as an issue more for minority patients than for white patients. Black and Hispanic patients consistently reported that barriers such as distance, access to an automobile, and availability of someone to drive them to the treatment center were potential major problems. The distance to the facilities was farther for whites than for blacks and Hispanics. Patients generally had to travel farther for chemotherapy than for radiotherapy.

**CLINICAL IMPLICATIONS:** Patients, particularly minorities, may opt to forgo needed care in the absence of available and affordable means of transportation to treatment facilities. These findings demonstrate the need for healthcare providers to be aware of the transportation problems that patients with cancer experience in obtaining treatment. Healthcare providers must work with patients, their families, and volunteer agencies in the community to facilitate transportation to cancer treatment services.

**KEY TERMS:** barriers, distance, location, transportation

Long-term illnesses such as cancer require extensive medical treatment. There are many psychological, social, and economic barriers that patients with cancer must overcome to obtain needed treatment.<sup>1-3</sup> Because of the need for repeated visits for treatment on either an outpatient or an inpatient basis, one of the major issues that patients with cancer must confront is how to arrange for transportation to care. Most studies have focused on the transportation barriers to mammography and prevention services.<sup>4,5</sup> Kiefe et al<sup>4</sup> showed that low-income, inner-city populations of women 65 years of age and older experienced transportation problems even when they were provided a voucher to defray costs of the mammogram. In situations in which there are limited costs for services, transportation still may remain a barrier.

A study by Goodwin et al<sup>6</sup> of persons 65 years of age or older living in New Mexico found that failure to receive definitive therapy for cancer was the result of impaired access to transportation and poor social support. According to McKenna,<sup>7</sup> compliance with treatment usually is good if transportation is available. Studies by Mor et al<sup>8-10</sup> documented that patients with cancer often experience many barriers, such as not having someone to drive them to the facility, the distance to the facility, and out-of-pocket costs associated with paying for transportation and treatment.

Bryan et al<sup>11</sup> found that transportation needs for economically disadvantaged patients with cancer were particularly problematic. Respondents from the Regenstrief Institute for Healthcare of Indiana reported several problems

Jeffrey J. Guidry, PhD, Assistant Professor, Department of Health and Kinesiology, Texas A & M University, College Station, Texas.

Lu Ann Aday, PhD, Professor, Behavioral Sciences and Management and Policy Sciences, University of Texas School of Public Health, Houston, Texas.

Dong Zhang, MS, Research Associate, University of Texas Medical Branch, Office of Biostatistics, Galveston, Texas.

Rodger J. Winn, MD, Director, Community Oncology Program, University of Texas M.D. Anderson Cancer Center, Houston, Texas.

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Address for correspondence: Jeffrey J. Guidry, PhD, Texas A & M University, Department of Health and Kinesiology, MS 4243, College Station, TX 77843.

with transportation to the clinics, including the cost of transportation or parking, the inadequacy of parking facilities, and the need for patients to ask others for a ride. More than 2% of the respondents reported missing clinic appointments because of transportation problems.

Studies have not focused directly on assessing the racial/ethnic differences in transportation to cancer treatment services. This information would help to identify those groups who are most at risk for experiencing barriers to receiving cancer treatment. This study compared the distance and mode of transportation to radiotherapy and chemotherapy and perceptions of transportation as a barrier to care. The responses of white, black, and Hispanic cancer patients receiving treatment from a consortia of cancer treatment facilities in Texas were analyzed and compared.

## Methods

### Study Objectives

An analytical cross-sectional survey was conducted to determine the prevalence of barriers to cancer treatment in Texas as perceived by patients diagnosed with cancer. Results reported in this article cover the role of distance and access to transportation as a potential barrier to treatment. Specific objectives of the analyses undertaken were to examine racial/ethnic differences in 1) the availability of chemotherapy and radiotherapy services and 2) transportation problems as a perceived barrier to cancer treatment.

### Study Sample

A mail questionnaire was developed to assess the perceived barriers to cancer treatment in Texas for patients with cancer 17 years of age and older who had been diagnosed clinically with breast, colon, cervical, or prostate cancer, or lymphoma between 1989 and 1993. Patients were instructed to base their answers on their perception of possible barriers during treatment, even if they had already completed treatment. The sampling frame for this study was obtained from a network of cancer treatment facilities throughout the state of Texas within the University of Texas M. D. Anderson Cancer Center Texas Community Oncology Network (T-CON). Six institutional consortia are part of the T-CON network, representing 20 individual institutions and more than 10,000 patients with cancer. The core consortia institutions are located in major metropolitan areas throughout the state, with affiliates in neighboring small towns and rural areas.

Each T-CON member was asked to provide data on the number of current patients by race/ethnicity for colon, cervical, prostate, and breast cancer, and lymphoma. The sample selection process involved a disproportionate systematic random sample. Minorities (blacks, Hispanics, and Asian-Pacific Islanders) were oversampled relative to whites. All T-CON sites received institutional review board approval before the beginning of the study. Informed consent was based on the completion and return of the

survey, for which a cover letter explaining the purpose and benefits of the study was provided.

### Survey Instrument

The survey instrument included questions pertaining to patients' perceived barriers to cancer treatment, as well as questions related to the diagnosis and duration of their cancer, use of and access to chemotherapy and radiotherapy services, the type of sources consulted regarding information about treatment options and the helpfulness of each informational source, and the use of and satisfaction with support groups and other informal networks of social support. Questions related to the patients' insurance coverage and demographic characteristics also were included. The questions were derived using an extensive literature search on barriers to treatment, discussion with focus groups of patients with cancer, and a pilot test with a representative sample of patients with cancer. The results reported in the present study involve specific questions pertaining to the location and distance traveled to received radiotherapy and chemotherapy, mode of transportation, and barriers experienced by patients with cancer in obtaining needed treatment. Patients were asked, "Based on your experiences, how much would you agree that each of the following (e.g., distance from treatment center, access to car or truck, finding someone to drive you to treatment center) can keep a person from seeking treatment?" Response categories were as follows: strongly agree, agree, uncertain, disagree, or strongly disagree.

The Aday/Andersen Access to Medical Care Model<sup>12</sup> was used to guide the organization of the major predictors of barriers. The three major components of the model include predisposing, enabling, and need factors. The predisposing factors include age, gender, marital status, and education. The enabling factors include household income and insurance status. The need factors pertain to type and duration of cancer. The model was used to identify which of the potential barriers for which questions that were posed were perceived as barriers by these patients.

### Survey Procedures

A total of 910 surveys were mailed to prospective participants. The Dillman Total Design Method<sup>13</sup> guided the survey development and administration process. A total of 593 patients with cancer returned their surveys, yielding a response rate of 65.2%. By racial background, the respondents consisted of whites (42%), blacks (40%), Hispanics (15%), and "other" (3%). A random sample was taken for whites and the universe for blacks and Hispanics and others. There were more than 850 white patients in the available study sample compared with only 550 minority patients. Therefore, because of the number of minorities available for the sample, this study included all minority study participants. A nonresponse analysis of respondents and nonrespondents showed significant differences by race and type of cancer.

Weighting adjustments then were made to correct

for differential sampling and response rates by racial groupings and type of cancer. All of the analyses involved the use of adjusted weights. Because the primary focus of the research was to examine racial/ethnic differences in perceived barriers to cancer treatment, tests of differences between racial/ethnic groups were conducted, using bivariate analyses and associated chi-square tests of significance. These analyses report the white, black, and Hispanic comparisons. Responses from the racial group reported as other (Asian-Pacific Islanders) were excluded because of the small number of cases ( $n = 13$ ) available for analysis.

## Results

### Description of Sample

The respondents ranged from 17 to 91 years of age. The mean age for respondents was 61.2 years, with a standard deviation of 15.2 (Table 1). The majority of the white and black respondents were 51 years of age or older, whereas more Hispanic patients were between 19 and 40 years of age ( $P < 0.001$ ). The majority (more than 60%) of respondents among black and Hispanic groups were women, while the white group showed an even distribution of male and female respondents ( $P < 0.05$ ). More than 70% of the white and Hispanic participants and approximately half of the black respondents (56%) were married ( $P < 0.001$ ). The norm-married category included patients who were separated, who were divorced, or who had never been married. The level of education completed showed that the white population had higher levels of education than the Hispanic and black participants ( $P < 0.001$ ).

Nearly 16% of the respondents did not provide data on household income ( $n = 96$ ). Among those who did respond, approximately 54% of Hispanics and 46% of blacks had annual household incomes of less than \$15,000 compared with only 19% of whites. Twenty-seven percent of Hispanics, 23% of blacks, and 22% of whites had incomes between \$15,000 and \$24,999. A marked difference was that more than 31% of whites had incomes of \$50,000 or more compared with only 5% to 6% for both blacks and Hispanics ( $P < 0.001$ ).

The major significant differences by type of cancer were between Hispanics versus black and white groups. One third (34%) of Hispanics had cervical cancer compared with only 7% and 9% of white and black respondents, respectively. However, approximately one third of the black and white respondents and only 18% of Hispanic respondents had prostate cancer ( $P < 0.05$ ). In all three racial groups, most patients had had the disease for 1 to 5 years. Differences in the duration of cancer between the racial groups were not statistically significant ( $P < 0.05$ ; see Table 1).

### Chemotherapy

Most respondents received their chemotherapy at a hospital outpatient department. Four of ten (42%) whites

**Table 1. Demographic Characteristics Of Sample by Race\***

Characteristic	White (%)	Black (%)	Hispanic (%)	Total (%)
<b>Predisposing</b>				
Age (yrs) ( $n = 565$ )				
≤18	5.9	11.2	4.9	7.5
19-40	6.3	10.4	17.3	9.5
41-50	8.7	14.1	28.4	13.7
51-60	15.8	16.9	13.6	15.9
≥61	63.2	47.5	35.8	52.8
$\chi^2 = 26.8$				
$P < 0.001^{\dagger}$				
Sex ( $n = 566$ )				
Men	50.2	39.2	32.5	43.2
Women	49.8	60.8	67.5	56.8
$\chi^2 = 10.6$				
$P < 0.05^{\dagger}$				
Marital status ( $n = 562$ )				
Married	75.3	55.7	72.2	66.7
Nonmarried	10.4	28.5	16.5	19.1
Widowed	14.3	15.7	11.4	14.2
$\chi^2 = 23.7$				
$P < 0.001^{\dagger}$				
Education (yrs) ( $n = 565$ )				
1-6	4.4	12.9	44.9	6.7
7-11	9.6	21.5	8.9	20.9
12	24.9	26.6	19.2	24.6
≥13	61.0	39.1	26.8	47.7
$\chi^2 = 101.6$				
$P < 0.001^{\dagger}$				
<b>Enabling</b>				
Household income ( $n = 497$ )				
\$15,000	18.8	46.5	53.5	35.2
\$15,000-\$24,999	21.6	23.3	27.0	23.3
\$25,000-\$49,999	28.4	24.8	14.9	24.8
≥\$50,000	31.3	5.6	5.4	16.7
$\chi^2 = 62.4$				
$P < 0.001^{\dagger}$				
<b>Need</b>				
Type of cancer ( $n = 568$ )				
Cervix	6.8	9.1	34.3	10.7
Lymphoma	4.8	1.7	6.3	3.6
Breast	37.5	44.2	34.3	40.8
Prostate	37.1	34.6	17.7	32.9
Colon	10.8	7.4	7.6	11.8
$\chi^2 = 16.4$				
$P < 0.05^{\dagger}$				
Duration of cancer (yrs) ( $n = 560$ )				
< 1	10.3	17.8	9.9	13.4
1-3	53.8	47.9	40.7	49.5
≥6	21.3	26.9	37.0	25.9
$\chi^2 = 14.6$				
$P < 0.05^{\dagger}$				

\*All percentages are based on weighted data.

<sup>†</sup>Significant  $P$  value.

Table 2. Location and Mode of Transportation: Chemotherapy by Race\*

Availability of Chemotherapy (n = 220)	White (%)	Black (%)	Hispanic (%)	Total (%)
Source				
Private doctor's office	41.8	27.1	2.9	30.1
Hospital outpatient department	48.1	57.7	67.7	54.4
Hospital inpatient	10.3	14.9	29.4	15.5
$\chi^2 = 2.2$				
$P > 0.05$				
Mode of transportation				
I drive myself	36.4	22.4	11.8	26.3
Someone else drives me	62.3	64.1	64.7	63.4
Taxi	0.0	2.8	2.9	1.8
Bus or other public transportation	1.3	2.8	8.8	3.5
$\chi^2 = 14.1$				
$P > 0.05$				
Distance (mi)				
≤ 10	37.7	36.7	14.7	34.5
11-25	16.8	22.0	23.5	19.9
26-50	12.9	25.7	41.2	23.5
≥ 51	32.5	15.6	20.6	22.1
$\chi^2 = 24.3$				
$P < 0.05^{\dagger}$				

\*The results are based on only those respondents who have received chemotherapy.

<sup>†</sup>Significant P value.

reported receiving their chemotherapy at a private doctor's office compared with 27% of blacks and 3% of Hispanics. More Hispanic respondents (29%) reported receiving their chemotherapy as hospital inpatients than black (15%) or white (10%) patients. Respondents also were asked about their mode of transportation (driving themselves, someone else driving them, taxi, ambulance, bus or other public transportation). More than 63% of all respondents reported having someone else drive them to receive their chemotherapy. The second major mode of transportation was driving themselves. This was more often the case for whites (36%) than for blacks (22%) and Hispanics (12%). The use of the bus or public transportation was more common for Hispanics (9%) than for whites (1%) and blacks (3%). Whites and blacks were more likely to report traveling 10 miles or less to obtain chemotherapy than Hispanics. Six of ten Hispanics (6%) and four of ten whites (15%) and blacks (41%) traveled more than 25 miles for treatment. In addition, more whites (33%) reported traveling more than 51 miles to receive treatment compared with blacks (16%) and Hispanics (21%) (Table 2).

### Radiotherapy

Overall, most radiotherapy treatments are provided on an outpatient basis. However, the majority of the respondents preferred receiving their treatment at a hospital radiation center rather than a freestanding radiation center. More Hispanics (76%) and whites (68%) reported receiving their treatment from the hospital radiation center than

blacks (55%). The mode of transportation was distributed almost evenly between those respondents who drive themselves and those who have someone else drive them for their radiotherapy. Whites were more apt to drive themselves (61%) than blacks (45%) and Hispanics (21%). Two thirds (66%) of Hispanics reported having someone else drive them for their radiotherapy. Again, Hispanics relied more on public transportation to travel to their radiotherapy treatment than the other groups. More whites (42%) and blacks (42%) than Hispanics (24%) reported traveling 10 miles or less to receive their radiotherapy. More Hispanics (38%) traveled between 26 to 50 miles to receive treatment compared with 25% for blacks and 16% for whites. However, more whites (23%) than Hispanics (14%) and blacks (9%) reported traveling 51 miles or more to receive radiotherapy (Table 3).

### Barriers

Respondents who agreed or strongly agreed that distance to the treatment center, access to a vehicle, and finding someone to drive them to the treatment center could present problems in obtaining treatment were considered to have perceived barriers to treatment. Hispanics and blacks reported barriers more often than whites. Distance to the treatment center was a perceived barrier for more Hispanics (66%) and blacks (51%) than whites (37%). Having access to a car or truck also was perceived as a potential major barrier for more Hispanics (60%) and blacks (55%) than whites (38%). In addition, 62% of Hispanics and

Table 3. Location and Mode Of Transportation: Radiotherapy by Race\*

Availability of Radiotherapy (n = 222)	White (%)	Black (%)	Hispanic (%)	Total (%)
<b>Source</b>				
Private doctor's office	6.0	12.6	10.0	9.4
Radiation center	26.3	32.6	13.3	27.2
Hospital radiation center	67.7	54.7	75.8	63.4
$\chi^2 = 37.4$ $P < 0.001^\dagger$				
<b>Mode of transportation</b>				
I drive myself	61.2	45.3	20.7	46.3
Someone else drives me	37.8	43.2	65.5	44.8
Bus or other public transportation	0.0	9.5	10.4	6.7
$\chi^2 = 31.7$ $P < 0.001^\dagger$				
<b>Distance (mi)</b>				
$\leq 10$	42.4	41.9	24.1	39.3
11-25	19.2	24.7	24.1	23.1
26-50	16.2	24.7	37.9	22.3
$\geq 51$	23.3	8.6	13.8	15.2
$\chi^2 = 14.1$ $P < 0.05^\dagger$				

\*The results are based on only those respondents who have received radiotherapy.

$^\dagger$ Significant P value.

55% blacks, versus 37% of whites, reported that finding someone to drive them for cancer treatment was a barrier that could cause one to forgo needed treatment (Table 4).

## Discussion

The findings indicate that racial/ethnic groups differ with respect to where they receive cancer treatment, the distance to these facilities, and the need for assistance in getting there. White patients were more likely to receive their chemotherapy at the private doctor's office than were blacks and Hispanics. Hispanics in particular were more likely to receive chemotherapy on an inpatient basis.

These findings clearly document the need for assistance for patients with cancer in obtaining needed treatment. More than half of the respondents reported that they have someone else drive them for treatment. The treatment process not only involves the patient, but other individuals as well. Problems are likely to arise for minorities in particular who are more apt to rely on others to provide transportation.

Distance factors were greater for chemotherapy than for radiotherapy treatments. The longer distances to receive treatment present problems with respect to time lost from work and associated out-of-pocket costs. Hispanics' greater reliance on public transportation also may present particular problems in obtaining timely treatment.

In addition, differences found in gender, level of education, and level of income between white and minority

groups may further exacerbate these barriers. The fact that more than 60% of the black and Hispanic respondents were women, whereas the white population was evenly distributed, suggests that minority men are less likely either to be in treatment or to respond to the survey. Access to treatment may be influenced by education because patients with a higher level of education may be better able to understand different cancer treatment modalities than those with a lower level of education. The many courses of treatment necessary for patients with cancer may pose a barrier in the patients' understanding of the need for the treatment." Lower levels of household income, found in the present study in more Hispanics and blacks than whites, may play a major role in exacerbating cost-related barriers to treatment.

Overall, the findings point to the transportation-related barriers that patients with cancer, especially minorities, may experience in obtaining needed medical treatment. More blacks and Hispanics consistently reported that barriers such as distance, access to a vehicle, and availability of someone to drive them to the treatment center were likely to cause one to forgo treatment.

There are some limitations to this study. This study did not stratify rural and urban patients. This information would have provided more information on the extent of transportation problems. In addition, the recall of perceived barriers may pose an issue for those patients who were not currently receiving treatment and therefore had to rely on past experiences. These questions may be answered in future studies that document these factors as they relate to barriers experienced by patients currently under treatment.

Table 4. Perceived Barriers to Cancer Treatment: Percent Who Strongly Agree or Agree by Race\*

Perceived Barriers to Cancer Treatment (n = 564)	White (%)	Black (%)	Hispanic (%)	Total (%)
Transportation				
Distance from treatment center $\chi^2 = 27.2$ $P < 0.001^\dagger$	36.8	50.5	66.2	46.4
Access to car or truck $\chi^2 = 46.0$ $P < 0.001^\dagger$	37.5	54.8	59.7	47.6
Finding someone to drive you to treatment center $\chi^2 = 35.8$ $P < 0.001^\dagger$	37.3	55.3	62.3	48.1

\*Respondents were asked whether any of these barriers could cause one to forgo needed treatment.

<sup>†</sup>Significant P value.

## Clinical Implications

This study documents the role of transportation and its significance in cancer treatment. It points to the need for healthcare facilities to facilitate the provision of transportation assistance for patients with cancer. Importantly, minorities may be more at risk than whites for forgoing needed treatment because of lack of transportation. Extended family and friends also often incur costs in assisting patients with cancer in obtaining treatment.

Cancer treatment facilities could, for example, survey their patients regarding their need for transportation services. These data would assist with the development of programs to address these patient needs. This information would be very beneficial to the patient services and social work departments as well in developing services and resources. Programs such as van assistance services and arrangements with taxi services for reduced-rate fares would facilitate access to distant facilities. There also must be consideration of the needs of individuals who provide informal transportation assistance to patients, such as housing, parking, and travel costs.

In addition, American Cancer Society programs, such as the Road to Recovery, which provide travel assistance to patients with cancer through a buddy system, may be adopted and expanded by cancer treatment facilities. Other initiatives, such as the utilization of support groups and programs through churches as transportation resources for patients with cancer, should be explored.

Thus, this study documents the need for healthcare providers to work with patients, their families, and other volunteer agencies in the community to facilitate transportation to needed cancer treatment services. Patients, particularly minority patients, may be likely to opt to forgo needed care in the absence of available and affordable means of transportation to treatment facilities.

## References

1. Ganz PA, Schag CC, Cheng H. Assessing the quality of life: a study in newly diagnosed breast cancer patients. *J Clin Epidemiol* 1990; 41:175-186.
2. Lewis FM, Zahlis EH, Shands ME, Sinsheimer JA, Hammond MA. The functioning of single women with breast cancer and their school-aged children. *Cancer Pract* 1996; 4: 15-24.
3. Houts P, Yasko J, Kahn SB, et al. Unmet psychological, social and economic needs of persons with cancer in Pennsylvania. *Cancer* 1986; 58:2355-2361.
4. Kiefe CI, McKay SV, Halevy A, Brody BA. Is cost a barrier to screening mammography for low-income women receiving Medicare benefits? *Arch Intern Med* 1991; 151:1217-1224.
5. Kreher NE, Hickner JM, Ruffin MT, Lin CS. Effect of distance and travel time on rural women's compliance with screening mammography in an UP RNet study. *J Fam Pract* 1995; 40: 143-147.
6. Goodwin JS, Hunt WC, Samet JM. Determinants of cancer therapy in elderly patients. *Cancer* 1993; 72:594-601.
7. McKenna RJ. Clinical aspects of cancer in the elderly: treatment decisions, treatment choices, and follow-up. *Cancer* 1994; 74: 2107-2117.
8. Mor V, Guadagnoli E, Wool M. An examination of the concrete service needs of advanced cancer patients. *J Psychosoc Oncol* 1987; 5:1-17.
9. Mor V, Guadagnoli E, Wool Xi. The role of concrete services in cancer care. In: Goldberg RJ, ed. *Psychiatric Aspects of Cancer*. Basel, Switzerland: Karger; 1988: 114-134.
10. Mor V, Masterson-Allen S, Houts P, Siegel K. The changing needs of patients with cancer at home. *Cancer* 1992; 69:829-838.
11. Bryan JL, Gfeger HA, Miller ME, Weinberger M, Loehrer PJ. An evaluation of the transportation needs of disadvantaged cancer patients. *J Psychosoc Oncol* 1991; 9:23-35.
12. Adav LA, Andersen R. A framework for the study of access to medical care. *Health Serv Res* 1974; 9:208-220.
13. Dillman DA. *Mail and Telephone Surveys: The Total Design Method*. New York: Wiley; 1978.
14. Wells ME, McQuellon RP, Hinkle JS, Cruz JM. Reducing anxiety in newly diagnosed cancer patients. *Cancer Pract* 1995; 3: 100-104.

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