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Increase Cancer Center Grants More Than R01s, SPOREs, Report Tells NCI

The NCI cancer centers are so effective in what they were designed to do that their grants should grow at a greater rate than R01 grants and Specialized Programs of Research Excellence grants, a report by an NCI advisory committee said.

The 61 NCI-designated cancer centers are research powerhouses that help scientists at their institutions win over half of NCI's extramural research budget, about $1.6 billion a year, said a report by a working group of the National Cancer Advisory Board.

However, the centers program is in danger of being eclipsed by the SPORE, disease-specific grants that on average are worth more per year—$2.55 million—than half of the existing Cancer Center Support Grants, the report said. NCI should hold the growth of SPORE grants to a rate no

(Continued to page 2)

In Brief:

Arnold Levine Named Professor At UMDNJ; Fox Chase Official Heads Association

ARNOLD LEVINE was appointed professor of pediatrics at the University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School and a member The Cancer Institute of New Jersey. Levine is known as the co-discoverer of the p53 tumor suppressor gene. He has been a member of the National Academy of Sciences since 1991 and served as chairman of the National Cancer Policy Board for the Institute of Medicine. Levine was president of Rockefeller University. Before joining Rockefeller University in 1998, he was the Harry C. Weiss Professor of the Life Sciences at Princeton University, where he founded the molecular biology department. Levine was chairman of the molecular biology department at SUNY-Stony Brook School of Medicine prior to his work at Princeton. Levine holds a doctorate degree in microbiology from the University of Pennsylvania and conducted post-doctoral work in virology at the California Institute of Technology. He has been awarded honorary degrees for his work in cellular and molecular biology from the University of Pennsylvania, the University of Pierre and Marie Curie in Paris, the State University of New York at Binghamton, York University in England, and the Mount Sinai School of Medicine. . . . **PATRICIA HARSCHE**, vice president of planning, business development and regulatory affairs at Fox Chase Cancer Center, has been elected president of the Association of University Technology Managers, a nonprofit

(Continued to page 8)

Centers Should Be "Centerpiece" Of Cancer Program, Report Says

(Continued from page 1)

greater than that of the R01 budget, the report said.

The centers program "should be a centerpiece of the nation's cancer research investment," while the SPORE program "has been an important new addition to NCI's efforts in translational research and has served as a complement to the Cancer Centers Program," the report said.

Also, NCI should streamline the review process for center grants, provide partial salary support for clinical investigators, and support cancer control and early detection research and outreach to state agencies and the Centers for Disease Control and Prevention, the report said.

"The Cancer Centers Program is 30 years old and in many respects it is the centerpiece of the NCI's effort against cancer," said Arthur Nienhuis, director of the St. Jude Children's Research Hospital and co-chairman of the committee. "It is a way to focus resources, organize and foster multidisciplinary, interactive research, and particularly, to undertake translational research."

In a presentation to NCAB earlier this month, Joseph Simone, a cancer center consultant and co-chairman of the committee that wrote the report, said a survey of 50 of the 61 centers provided data on the dollar magnetism of the centers.

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On average, a cancer center receives $2 million a year from its Cancer Center Support Grant, which funds the research infrastructure. On top of that, an average center is able to bring in about $55 million a year in sponsored projects and other grants, about $1.5 million a year in institutional funds, and about $3 million in gifts, Simone said.

"The Cancer Centers Program is strong; it's the site of most translational cancer research being done in this country," said Simone, former medical director of the Huntsman Cancer Institute at University of Utah.

The 61 center grants, known as P30s, consumed 6.6 percent of the NCI budget in fiscal 2002, nearly $192 million.

The SPORE, or P50 grants, were started in 1992 to foster disease-specific translational research. NCI currently funds 44 SPOREs, 41 of which are held by cancer center investigators, for a total of $95 million in FY 2002, about 3 percent of the NCI budget.

"Two sources of growing imbalance in the P30-P50 relationship…could be troublesome in the future," the report said.

First is the concentration of SPORE grants in centers: five centers hold 19 SPOREs. Second, funding for SPOREs has increased rapidly in the past five years, and the monetary size of these grants threatens to overshadow the center grants, the report said. Nearly half of the center grants have annual awards that are less than the average annual SPORE grant of $2.55 million.

"Both programs are outstanding and could benefit from significant funding expansion," the report said. "Cancer centers in particular provide the research infrastructure needed for an increasingly complex array of discovery-oriented translational and clinical research objectives."

The report advised NCI to:

—Phase out the Cancer Center Planning Grants, or P20s, because that program has had little success in helping institutions become full-fledged cancer centers.

—Provide more flexibility for SPOREs, but make the review more rigorous by moving to a two-tiered review system.

—Reward centers for cooperating with SPOREs.

—Consider funding "junior cancer centers" to work with established centers.

—Include cancer center directors in NCI's strategic planning process.

The report also suggested that NCI organize the clinical trials system more efficiently, and harmonize guidelines for centers, SPOREs, the Community Clinical Oncology Program, and clinical trials cooperative groups.

"A Self-Fulfilling Prophecy?"

From NCI's appointment of the P30-P50 Working Group—which consisted primarily of cancer center officials and individuals with ties to institutions that hold center or SPORE grants—to its charge to the committee, it was clear that the Institute wasn't looking to challenge the cancer centers system.

"Our first goal was, how can we shape these programs to continue to do what they're doing, but enhance their capacity to maximize translational research," Nienhuis said to the NCAB at its Feb. 11 meeting.

Nienhuis said the centers' role at NCI should be increased.

"It was an important challenge to us to suggest ways in which the centers and the SPOREs could play a greater role in setting the NCI agenda, thereby assuring that there was a flow of NCI support and prioritization through the centers in the context of their having helped formulate the goals," Nienhuis said.

Not everyone agreed that centers should get more money and influence. NCAB member Susan Love said she was concerned about the appearance of centers "taking over" cancer research.

"It was a very good report, but I have some real concerns, and I think I have to be the devil's advocate here," Love said. "First of all, there is sort of a conflict of interest, because almost every single person on that committee was involved in a cancer center, so that the fact that it came out thinking cancer centers are great and should be sustained and improved was almost a foregone conclusion. You had two advocates and that's it.

"The fact that 50 percent of the NCI's extramural funding is in cancer centers—they really are strong and powerful, and I sort of worry," Love said. "I hear this as the cancer centers taking over cancer in the United States. The idea of let's expand them, and we'll put new cancer centers under the old cancer centers, and we'll have the cancer center directors have a bigger role in the strategic planning of the National Cancer Institute, and we'll connect them now with the CDC.

"It may be the right thing to do, maybe that's the way to have a network, and the way we should have the cancer program organized in the United States, but I think if that's what we're going to do, we need to say that outright and look at it in that way," Love said. "It sort of feels like a sneaky way of having the cancer centers take over. I don't in any way question your motives or think that's what you are doing, but that's what it sounds like from somebody who is not involved in cancer centers.

"If we are going to do that—and it may well be the right thing to do—then we need to do it in a conscious way," Love said.

"My one other pet peeve is the implication of the cancer centers that the NCI is endorsing the clinical care," Love said. "Certainly the cancer centers I've been involved with used that to the utmost, and yet there's nothing in the grant, there's nothing in any of the review that has anything to do with clinical care. I think that's false advertising. It's a little bit of a charade that goes on in this country, that when you are an NCI cancer center, the public thinks that means that the NCI has checked out the level of care and thinks it's good. We all know that hasn't happened, and we all just pretend it isn't true."

NIENHUIS: We were certainly cognizant of the fact that in articulating the central role of the cancer centers in facilitating and integrating research that we were open to the potential of conflict of interest. There was a genuine feeling on the working group that the centers as they have been organized with the focus within academic medical centers and the emphasis on developing relationships with surrounding elements in the cancer effort really do have a central role, fundamentally. Not that cancer centers should take over, and we didn't recommend that, but that they should serve as a hub within their region to develop interactions that would better coordinate, better focus, both dissemination of knowledge and delivery of knowledge, and sustain their research efforts.

SIMONE: We worried about this, and I'll point out to you that we didn't pick us. Four people had no official relationship with cancer centers, including myself.

The 50 percent number is impressive, but it goes to the institutions. The actual amount of money that cancer centers get is a considerably smaller slice, but it's still substantial.

We certainly don't want to take over the world. Eighty percent of all the clinical research in this country is done in community settings right now.

That's not likely to change. I think what we were saying is that we ought be cognizant of that, we ought to reach out, and there are other organizations that desperately would like to be cancer centers but can't make the cut.

I couldn't agree with you more about the quality of care issue. First of all, most people don't know what NCI is, don't know what a cancer center is, or whether it's NCI-approved. But those who do assume you are going to get better care there. That's sometimes true, and sometimes it's not true. The problem is, NCI considers itself a research organization, not in the care delivery business. So the fundamental question is how far out into the application world, the communication world, and the quality of care world, does NCI wish to go?

LOVE: The NCI has to decide whether either it's going to go out there and look at the quality of care, or it's going to say to the cancer centers, 'You can't use this designation to imply that it approves your care.' We shouldn't be in the gray zone.

My only other comment is, the fact that 50 percent of the extramural funding is within the cancer centers: it's partly, too, because the peer review people come from cancer centers. It gets to be a whole self-fulfilling prophecy, and I think one of the things that at least some of the advocate groups I'm involved with are concerned with, is we keep on doing the same-old, same-old stuff. There is not really a lot of room for innovation, and part of that is the structure. So that you have people who at some level do have a conflict of interest reviewing the grants. They may be peers, but we all know there is still a conflict of interest going on there at some level. So you can just keep redoing the same stuff, and maintaining the same structure. Maybe that's what we want to do, but I would like to think that we might want to look for mechanisms where we can also break out of that.

I don't think we throw it out, because it served us in good stead to a large degree, but I think it also has prevented us from getting as far as we can go. Maybe there's a way we can do both.

More and more, all the SPOREs are in the cancer centers, it starts getting to be the same people doing everything, and that really does restrict new ideas and new approaches.

LARRY NORTON (NCAB member and an oncologist at Memorial Sloan-Kettering Cancer Center): I'm of the opinion that good clinical research is good clinical care.

LOVE: There are places I've been where the care is not very good, and the research is great, and they still make the claim.

NORTON: I don't want to get into that. That people are involved in peer-reviewed clinical research, to me, is a very important step for preserving and promoting quality.

"A Treasure To Protect At All Costs"

James Armitage, dean of the University of Nebraska College of Medicine, and an NCAB member who served on the P30-P50 committee, defended the cancer centers.

"I would argue that this is probably, if not the most important thing that NCI has done, maybe that NIH has done, if you want to look at the impact it has had on the field of medicine," Armitage said. "If you go around to universities in the United States, if it has a cancer center, that cancer center director is somebody who reports to the vice president or the dean.

"It's a large, important structure the universities would kill to keep, and it forces the university to support cancer," Armitage said. "I would imagine if you were a cardiologist or an endocrinologist or a whole bunch of other things, you'd wonder how it was that we pulled this off. We turned the focus of universities so much toward something we think is important. It would be difficult to overestimate the impact of this thing that started a little bit more than three decades ago.

"This is a treasure of the country and, certainly, if you are interested in cancer, it's incredibly important and something we want to protect at all costs," Armitage said.

NCAB member Ralph Freedman, of M.D. Anderson Cancer Center, said the report appears to de-emphasize the role of R01 grants. "If we don't continue to support those individuals at an acceptable level, you make get disinterest in the part of people wanting to go into science, and then we won't have a critical mass of scientists within institutions who can contribute to translational research," he said.

"That's the lifeblood of cancer centers," Simone said. "If you don't have basic science, you don't have a cancer center. It's the scientific engine of most cancer centers. R01-based research is the fundamental underpinning of a cancer center."

Franklyn Prendergast, NCAB member and director of the Mayo Comprehensive Cancer Center, said the center grant focuses research efforts.

"I, too, noticed the relatively stilted composition

of the committee and worried about it simply because I'm in a matrix organization, and I think matrix cancer centers face a lot of fundamental issues, at least by analogy to what Dr. Love is talking about," Prendergast said. "It's an issue I've given a great deal of thought to, because being in a matrix organization we've had to face a lot of criticism regarding the seeming dominance of the cancer center and of the SPORE program in terms of its influence on the institution.

"The cancer center is a wonderful mechanism for focus, and for bringing a sort of discipline of coherence and cohesiveness that has not been there by virtue of any other mechanism that I've seen in research over the last 25 years," Prendergast said. "The SPORE program has done something similar. The influence is spreading beyond cancer into cardiovascular, endocrinology, who have seen there is such a tremendous advantage to bringing people together who have common interests. These spin-off benefits are seldom considered. They are tangible, they are real, and they are quantifiable.

"It's not really surprising to me that the influence is being felt in terms of the R01 pool, that centers have leveraged up to 50 percent of the [research] funding of the NCI," Prendergast said. "The fundamental question comes to whether the peer group process is fair, or whether it is stilted, and that's a much broader issue."

"Gravitational Force" of Cancer Centers

NCI Director Andrew von Eschenbach said the report will serve as a "starting point" for the Institute to develop an "implementation strategy" for the recommendations.

"We now have a very comprehensive, insightful review upon which we can begin to discuss, debate, deliberate, and most importantly, make decisions," he said.

"When I arrived here a year ago and began to immerse myself in the business of the NCI, one of the very important, critical issues that rapidly surfaced was the extraordinary growth that Joe and Art alluded to within these programs, and the extraordinary expectations that were generated on the part of the future direction of these programs," von Eschenbach said. "This report, the opportunity to step back, and to begin the process by first, as Susan pointed out, asking those people who were most knowledgeable and closest to the process to at least begin to formulate the issues that were critically important, and now to take that to a much larger audience, has been an extremely important initiative….

"I think this whole issue of what has happened with regard to cancer centers in this country is absolutely extraordinary in the past 30 years," von Eschenbach said. "They have become incredibly important platforms. When one recognizes that 41 out of 44 SPOREs, without design, developed within cancer centers, there is a gravitational force that's occurred."

The report documented that the centers "really are drawing resources to them," von Eschenbach said. "It opens the question, 'Do we need to pay attention to keeping that in balance so that we make sure that we don't shift the pendulum all the other way, and what was a great strength now becomes your Achilles' heel because there's nothing else?' So we at least are in a position now to be thoughtful about how we go forth."

NCI is planning similar review of its clinical trials and basic research programs, von Eschenbach said.

The report of the P30-P50 Working Group, titled "Advancing Translational Cancer Research: A Vision of the Cancer Center and SPORE Programs of the Future," is available at: http://deainfo.nci.nih.gov/ADVISORY/ncab/p30-p50/P30-P50final12feb03.pdf

Executive Summary:

National Cancer Institute (NCI)-Designated Cancer Centers, funded through the P30 mechanism, play a fundamental role in the nation's cancer research agenda. These centers are unique entities where discovery, development, and delivery come together to make progress in the alleviation of the burden of cancer. As such, they are a model of translational research, unparalleled by any other national effort in any disease area. In an embattled health care system, the NCI Cancer Centers Program provides the nation with an extraordinary opportunity to address one set of diseases in a comprehensive manner, relying on the best science, clinicians, community networks, and patient groups to improve the quality of care.

Members of the 39 comprehensive cancer centers, 14 clinical cancer centers, and 8 basic cancer centers are responsible for more than 50 percent of the entire NCI research portfolio. In addition, NCI-Designated Cancer Centers have facilitated the application of major discoveries in molecular and cellular biology to cancer care through partnerships with NCI and industry. NCI leadership must capitalize on these centers and their institutional prestige to most

effectively translate and disseminate methods of improved cancer care and innovation to the American public.

In addition, during the last decade the Specialized Programs of Research Excellence (SPOREs)—funded through the P50 mechanism—have embraced and increased the impact of translational research, a previously under-funded and under-appreciated area. SPOREs in multiple organ sites have advanced translational research, creating a new career path for joint clinical and basic science investigations. As befitted a new program area, the SPORE structure created through peer review self-contained, large research programs with a critical mass at single institutions, typically NCI-Designated Cancer Centers.

Because translational research has now matured and budgets are flattening, NCI is seeking mechanisms for improving the efficiency and integration of its P30 and P50 programs, while at the same time maximizing the number of institutions performing translational research. Under the auspices of its Subcommittee on Cancer Centers, the National Cancer Advisory Board convened an ad hoc P30/P50 Working Group to examine the P30 and P50 award mechanisms in terms of how they might best be positioned to support and facilitate increased discovery and translation of research into the future.

The recommendations of the Working Group are grouped into three overarching themes, as summarized below: 1) understanding the implications of budgetary issues; 2) expanding the roles and expectations of centers and SPOREs; and 3) increasing the efficiency and effectiveness of these funding mechanisms. More elaborate discussion and detailed recommendations can be found in the full report.

Recommendation 1: The Cancer Centers Program and SPORE program are vital components of NCI's translational research efforts and must be sustained, even in today's challenging financial environment.

1.1 The P30 cancer centers are the engine of NCI's extramural research program and are the bases for community outreach and dissemination to the wider research and geographic communities. In the short term, funding can be stretched by limiting growth to slightly above that of R01s and by suspending the P20 program due to its limited success in leading institutions to an eventual P30 award.

1.2 Despite its success, the P50 SPORE program cannot grow at its present rate. It can be sustained by a) slowing its growth to a rate not greater than that of the R01 mechanism; b) lowering the average cost per award in part by reducing the number of required projects and elements; c) allowing SPOREs to focus on pathway, mechanism, or population research; d) fusing appropriate shared resources with those of the P30 in a given institution; and e) implementing a program requirement for matching NCI funds with other sources of non-federal and philanthropic support.

Recommendation 2: NCI should take better advantage of the entrepreneurship and vitality of cancer centers by systematically and routinely engaging them in NCI's strategic planning and budgetary discussions. Furthermore, to leverage the existing strengths of cancer centers, NCI should encourage the development of novel research resources, dissemination techniques, and community collaborations. Specifically, NCI should:

2.1 Include cancer center directors on a regular basis in NCI's strategic planning process, providing them the opportunity to offer guidance in developing new NCI initiatives and disseminating research findings.

2.2 Look to centers as sites for piloting new research and dissemination programs to assure cost-effective integration with existing resources.

2.3 Allow salary support through the P30 award for clinical researchers who actively engage in trials in recognition of the essential role these individuals play in translational research.

2.4 Revise the funding of P30 shared resources to provide more appropriate support for critical and underfunded activities, such as tissue banks and data management, and for essential new exigencies such as regulatory compliance.

2.5 Encourage geographic distribution by creating a new category of cancer center for academic institutions not able to meet all requirements of P30 applications; these institutions would be associated with and funded through an existing P30 center.

2.6 Provide support through the P30 mechanism for cancer centers actively seeking links with state health departments or other state agencies, or with the Centers for Disease Control and Prevention (CDC).

2.7 Modify the P30 award to encourage and support centers to develop infrastructure and test novel methods for disseminating new knowledge in clinical, cancer control, and early detection research.

Recommendation 3: NCI should make a concerted effort to improve the efficiency, effectiveness, and evaluation of the research processes in centers, SPOREs, and cooperative groups. Specifically, NCI should:

3.1 Adopt as a top priority the development of an integrated national clinical research informatics system.

3.2 Limit the additional review of clinical trials that are supported by previously peer-reviewed funding mechanisms to safety and regulatory issues.

3.3 Work with the federal Office for Human Research Protections to engage cancer center Institutional Review Boards in developing a strategy for centralized review of multi-center trials.

3.4 Streamline the review of P30s by eliminating the need for some site visits.

3.5 Adjust the P30 review process to consider and accord weight in scoring activities involving collaboration with P50s, cooperative groups, and participation in networks, as well as community service, outreach, and dissemination.

3.6 Initiate a planning process to develop quantifiable metrics for determining the size of the P30 award that reflect the broad spectrum of involvement of individual cancer centers in discovery, dissemination, and the delivery of care.

3.7 Employ a two-tiered system of review for the P50 SPORE program, with a parent committee empowered to review applications across sites from the perspective of managing the program in its entirety.

3.8 Develop a process to describe and quantitate on an annual basis the overall contributions of the P30/P50 programs.

This report contends that NCI-Designated Cancer Centers and the associated SPORE program are central to discovery and represent the best, most practical national network for testing and disseminating innovations that reduce cancer mortality. The strategic directions listed above and discussed in the full report will further improve the ability to translate and disseminate research advances.

Unfortunately, the next several years are likely to be a period during which overall NCI resources will at best be constrained in terms of growth in constant dollars, and at worst be reduced. Thus, in the short term, implementation of recommendations requiring funding can be accomplished only through 1) ensuring flexibility in the P30 and P50 mechanisms; 2) re-budgeting NCI funds, both within and outside the Cancer Centers Branch to achieve economies of scale; and 3) facilitating and establishing partnerships, such as those with industry for informatics and with CDC for dissemination initiatives.

However, because the opportunities are too great and the task too important to ignore, the Working Group looks to NCI leadership—with the help of cancer centers and SPORE leadership, advocates, and others—to seek substantial increased funding for the P30 and P50 mechanisms over the next three to five years. Full funding should result in an NCI-led, evidence-based outreach and dissemination effort; continuation of the world's finest discovery research infrastructure; a robust, integrated translational, clinical, and prevention trial apparatus that responds rapidly to innovation; increased patient accrual to clinical and prevention trials; new mechanisms for geographic coverage by the Cancer Centers Program; and an increase in the novelty and number of SPORE grants. The benefit to delivery, dissemination, and coordination will be easily demonstrable.

The cancer center and SPORE infrastructures, operating through the nation's leading public and private institutions, offer a critical link to the American people. Implementation and funding of these strategic initiatives will focus this unparalleled resource on discovery and development and demonstrably enhance delivery of the latest prevention, early detection, and therapeutic advances.

Funding Opportunities:

Program Announcement

PAR-03-074: Flexible System to Advance Innovative Research for Cancer Drug Discovery by Small Business—SBIR/STTR Initiative

The objective of this PAR is to provide a flexible funding mechanism with regard to budgets and time of award to support the research activities required to enable small businesses to bring their innovative efforts for drug discovery and development to clinical validation. Projects submitted in response to this PAR should be focused on discovery and development of a specific agent or class of agents.

The PA is available at http://grants1.nih.gov/grants/guide/pa-files/PAR-03-074.html.

Inquiries: George Johnson, Developmental Therapeutics Program, Division of Cancer Treatment and Diagnosis, NCI, 6130 Executive Blvd., EPN 8152, Bethesda, MD 20892-7456, (For express/courier service: Rockville, MD 20852), phone 301-496-8783; fax 301-402-5200; e-mail johnsong@exchange.nih.gov

In Brief:

Janice Nall, NCI Web Site Usability Expert, Recognized

(Continued from page 1)

association of managers and business executives who manage intellectual property. She was elected at the Feb. 7 annual meeting of the association . . . **JANICE NALL**, chief of the NCI Communication Technologies Branch, was named among the top 100 Federal executives from government, industry, and academia who had the greatest impact on the government information systems community in 2002 by Federal Computer Week. Nall was honored for her work on http://usability.gov, an NCI Web site where information is shared about usability engineering research. . . . **MITCHELL SMITH and RICHARD NOURIE** will receive the Lifetime Achievement Award from the Leukemia & Lymphoma Society Eastern Pennsylvania Chapter at its 4th Annual Legacy Gala, March 22. Smith, who is developing a murine model for mantle-cell lymphoma, is the director of lymphoma service at Fox Chase Cancer Center. Nourie, a retired businessman and society board member, is developing a donor committee. Also being honored are three corporations for their financial support: Verizon, Wyeth, and Penn Treaty Network America Insurance Co. **Dwayne Howell**, national president and CEO of the society, will present the awards. . . . **NATIONAL MARROW DONOR PROGRAM** named **Laurence Atlas** board chairman. Atlas is vice president of government relations for Loral Space & Communications of Arlington, Va. He succeeds **Nancy Kernan**, assistant chief of the Memorial Sloan-Kettering Cancer Center Bone Marrow Transplant Service. Kernan will remain as a board member. NMDP added five members to its board of directors: **Stella Davies**, director, Blood and Marrow Transplant Program, Cincinnati Children's Hospital Medical Center; **Christine Frisbee**, chairman, Richard D. Frisbee III Foundation of New York; **Robert Howard**, father of leukemia patient; detective, Seattle Police Department; **Mary Faith Marshall**, professor of medicine and bioethics, School of Medicine at Kansas University Medical Center; and **Raymond Wynn**, cancer center director and director of radiation oncology, Regional Cancer Center, Singing River Hospital System, Pascagoula, Miss.

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