Biomedical Technology Research Resources

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Evaluation of P41 Biomedical Technology Research Resources

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April 2007 Panel Report

EXECUTIVE SUMMARY

Relevance of BTRR to NIH mission

A panel of scientists and engineers from diverse backgrounds and institutions convened in April 2007 to evaluate the BTRR (P41) program of NCRR and to make recommendations regarding its evolution, balance, and mechanisms. This evaluation comes at a time when there is a major effort at NIH to encourage translation of basic medical science into clinical medicine. The panel recognizes the value of the BTRR program in supporting innovative basic science, and it strongly recommends that this program be continued. The panel also is concerned that funding for this unique and outstandingly successful program has remained static for the past 40 years, even as the program has promoted innovation, collaboration, and service in the basic sciences.

The panel proposes that the BTRR programs form a paradigm or backbone for the Roadmap initiatives of NIH, as well as for specific programs directed toward solving problems of health care in specific disease categories. Thus, as the new Clinical and Translational Science Award Program (CTSA) is being promulgated, one of the major conclusions of the panel is that the current BTRR program will provide an essential underpinning of the CTSA. This is true because almost all of the CTSA awards will benefit from the technology or the technical support of one or more of the 50 centers in the BTRR program.

Given the panel's strong support for the BTRR program in principle, the recommendations of the panel focus on issues regarding the portfolio balance within BTRRs; mechanisms of review and prioritization of proposals for funding; integration of the BTRR program with NIH activities; establishment of metrics that facilitate quality assessment and redirection of resources where necessary; methods of attracting talent to the leadership of continuing and new BTRRs; and the value of including an advisory committee specific to BTRRs. Three major areas of recommendation are summarized here.

Balance and Expansion

Though the panel does not recommend a major expansion, we note how important the BTRR program is for underpinning CTSAs and other efforts. Thus, the panel has proposed its recommendations both to improve the intrinsic strength of the BTRR basic science portfolio and to provide a better interface with the CTSAs. The panel felt strongly that, although the amount of funding for the BTRRs is small compared with that for the CTSA program, their vital role in underpinning the new program should neither be undervalued nor underfunded either now or in the future. That is, we believe that the success of the CTSA program will always be intrinsically linked to robust long-term support of the BTRR program. For example, biology/mass

spectroscopy and computational informatics are two areas of unmet needs where the BTRR program can move forward and align with clinical and translational science.

Metrics for evaluation
The panel recognizes that much of the true impact of BTRRs is likely to be found in inventions and discoveries whose importance was not immediately recognized, as well as in the training of successful medical scientists. Thus, we recommend that additional effort be made to provide a comprehensive metric of the value added by the BTRR program since 1960, so that its past and continuing importance to NIH can be fully appreciated. This activity would be an expansion of the work already initiated by staff.

Advisory Panel
We propose that an advisory panel be created to assist Council and NCRR leadership in the evaluation of the balance and quality of BTRRs, as well as in the best means to achieve integration with clinical and translational science. The program-level committee should include extramural scientists, particularly those who have been involved in the BTRR program in the past, as well as experts at the industry-academe interface.

THE BTRR PROGRAM OF NCRR

Advanced technology and specialized instrumentation are essential for progress in biomedical research. Often inspired by limitations of current methods, the expertise from physicists, engineers, and computer scientists is brought together at interdisciplinary centers, enabling the synthesis of novel solutions. The P41 BTRR program from NCRR has been the nation's most important sponsor for development of innovative technologies used in biomedical research, including electron microscopy, magnetic resonance imaging, positron emission tomography, cyber infrastructure devoted to neuroscience, the many applications of synchrotron radiation, optics and lasers, spectrometry, and many other advanced technologies that now serve medical science.

Instrumentation used in biomedical research varies. At one end of the spectrum is complex but relatively inexpensive desktop technology, such as PCs and turnkey devices for imaging or spectroscopy. At the opposite end are unique instruments with limited availability and evolving technology, such as grid-based supercomputing, ultra-fast optics, electron microscopy, multimodality imaging, and many others. In many cases it is appropriate for individual institutions and even solo investigators to acquire complex technologies once they have matured and become commoditized. Yet at the earliest stages of development, and at the limits of current methods and instrumentation, the most efficient and effective means of advancing technology is to concentrate the work at a few highly specialized centers that have assembled experts in the relevant disciplines, and that possess the organization and interest to synthesize solutions and demonstrate their results. This must be done in an open, collaborative manner, with dedication to community service and with sharing of methodologies as well as results.

In an ideal world, we would identify the most important needs and opportunities for technology development; assemble for each a highly skilled interdisciplinary team devoted to biomedical problem-solving; connect this group with established biomedical investigators that require new

or better technologies; train new investigators in the application of advanced methods; provide a means for access to the unique instruments and experts; and disseminate the results and technologies to the biomedical research community. The support provided to these groups would be leveraged on institutional and private resources to multiply the effectiveness and sustain the ongoing efforts of technology development groups to achieve highly specialized, unique and world-leading results.

The BTRR program strives to achieve these objectives by sponsoring the best-of-class in technology development, using a solicitation and review process that evaluates and prioritizes the most important aspects of a national research resource. This process uses criteria such as excellence in technology development, collaboration, service, training, dissemination and administration. Essential to implementing this program is the expertise of physical scientists, engineers, and computer scientists. The BTRR program is the most effective and broad-ranging mechanism that NIH has devised to bring this expertise to bear in the medical research environment. These Resources bring together the technical and medical expertise necessary at the frontiers of biomedical research. The program has an extremely impressive portfolio of instrumentation and expertise. Perhaps most importantly, the BTRR program is responsible in large part for the advances in bio-computing, imaging, optics, structural and systems biology that depend on unique technologies.

The NCRR BTRR P41 Program is peer-reviewed and, because of the large size, uniqueness, and complexity of the proposals, site visits are required to augment the written proposal and provide a comprehensive basis for reviewer evaluation. Reviewers are predominantly drawn from experts in fields other than technology development and thus can appreciate and evaluate the proposed research resources from the perspective of users who will ultimately apply the instruments and methods. The new technologies originate from unique groups of investigators and provide unexpected opportunities for advancement in the intended application. Yet they also facilitate the development of new and unanticipated applications. A high degree of institutional and private support, and often large-scale infrastructure support from other agencies, such as the Department of Energy, complements the P41 centers.

Today, this program supports superlative projects at some of the nation’s best known, most productive and unique biomedical and methodology centers. Despite the enormous past contributions of the BTRR P41 program to the nation’s preeminence in biomedical research, there remains a critical and immediate need to explore and develop new instrumentation and technology development opportunities to advance biomedical research, yet funding is severely constrained and the overall program has not grown. Only the elite institutions and groups are represented, and startup of new centers has been a rare event.

Where else can an investigator find scientists and engineers steeped in the technology, who are willing to invest time and effort to understand how that technology might be applied to a new biomedical problem? The deep technical understanding that a BTRR center accumulates in its focal area can be directed to new biomedical problem areas quickly and efficiently, much more so than could be done by the investigator alone or by collaborators unfamiliar with biomedicine. An environment where the technical expert is ready and able to learn about the biomedical problem and in which the investigator can readily access the technical tools is invaluable at the

scientific frontier. This symbiosis will be even more important as the NIH shifts its emphasis toward clinical and translational science.

BTRR COMPONENTS

Currently, each BTRR (P41) comprises five components: (1) core technology development, (2) collaboration, (3) service, (4) dissemination, and (5) training. The same balance in quality and quantity of effort in these five components is neither desirable nor practical for the 50 different centers. However, all centers must show some effort in the five components, and the evaluation of each center is based on whether it has achieved a level of excellence in those components that are most appropriate for a particular Resource. NCRR proposes adding a sixth component, *infrastructure*, which addresses activities and technologies that do not constitute research but support all technical projects within the overall resource. However, the committee notes that the great success of the BTRR program and its leadership has been well served by evaluation of the current five components, and it therefore does not see the need for an additional component.

Recommendation
Rather than add a sixth component area focused on infrastructure, improve instructions to applicants and reviewers, particularly by clarifying the definition of "core."

SCIENTIFIC COMMUNITY'S INTEREST IN BTRR

Although the BTRR program is highly innovative and underpins the CTSAs and other NIH efforts, the value of this program is poorly understood by the scientific community. Some investigators have declined to participate in the BTRR program because of misperceptions about the program, whereas others have been discouraged from applying at the staff level. In addition, the successes of the BTRR program have not been well advertised. The selection field of talent could or would be larger if more people were informed of the BTRR program and were educated about the application process.

NCRR should retain its R01 and R21 programs to continue encouraging individual investigators, particularly new investigators, and ways to nurture new or young investigators working with BTRR teams should be examined. Instead of counseling young investigators that their ideas do not "fit into the mission" of the NCRR, staff should encourage them to present their research plans, in order to nurture all facets of biotechnological development that could potentially serve any of the various NIH Institutes or Centers (ICs) or the extramurally funded community. There would be increased interest in these programs engendered by the nurturing of these mechanisms of funding, because these permit investigators to follow their own ideas and projects, while at the same time contributing to technology development or, at the very least, to new uses of these technologies. But these programs do not involve acquisition of equipment needed to launch or advance a new technology. Very few scientists want to become operators or managers of enterprises that do not incorporate their own research programs. In addition, the development of a new resource requires a high degree of altruism, because investigators are promising to make their technology available to a wide community of scientists at the earliest opportunity. This contradicts typical NIH funding mechanisms, which rely upon or promote competition between investigators.

The RFA system should be considered as a way to advertise the BTRR programs. Although these are strictly not investigator-initiated research programs, and although they carry the obligation of a budget allocation, RFA-driven programs will attract those who have a competence and passion for the designated area. Some agencies within the Department of Defense use a "Broad Agency Announcement" (BAA) to stimulate interest in a particular subject area that is usually a topic for engineering R&D, not an area of science and technology development. The new grants, as envisioned in NIH Program Announcement (PA) PAR-07-344, provide an excellent means for identifying and developing candidate groups to fill the evolving needs of the BTRR program as it continues to play a central role in translational research and development. NCRR should be involved in this PA. Again, the trans-NIH view should be encouraged in the development of these programs.

The evaluation panel is concerned that spending on this program has remained static since the program's inception, a period in which the overall NIH budget has quadrupled in inflation-adjusted dollars. The panel emphasizes that considerations of mechanisms to attract applications must accept the reality of the costs of review programs that would require site visits, as well as the costly nature of some of these biotechnologies.

The panel notes that, although the BTRR program is primarily investigator-initiated, there is some degree of NCRR staff initiation, as NCRR staff visit various sites and encourage investigators to submit applications. In addition, the committee is highly concerned about the amount of decision-making done within the NIH without consultation with those in the scientific community who actually conduct the research. Investigator-initiated research, which plays a large role in the nation's leading-edge research, should receive continued support. **This does not include PAs that define or circumscribe certain research initiatives generated by NIH staff to promote certain specified program areas.** The term "investigator-initiated" is to be taken literally and, if such funding is preserved, it will attract innovative proposals. Recently, these mechanisms have not been adequately supported by NCRR and, therefore, the scientific community has lost interest.

Recommendations

1. **Examine the reasons investigators decline to participate in the BTRR program, and use this information to improve BTRR program instructions and announcements.**
2. **Implement a pre-program, phase I mechanism that would allow 2 to 3 years for researchers to get an innovative technical idea under way or establish biological collaboration before devising an extensive plan for training, outreach, and other components. Instead of using the X02 mechanism, as proposed, the NCRR should revisit the R24 or P20 mechanism. This would ensure that productive technologies would be supported by the BTRR program.**
3. **Vitalize the R01/R21 program with an appropriate budget so that applicants with scores in the fundable range for other Institutes and Centers (ICs) can become part of the NCRR family.**

PROGRAM BALANCE

The April 13 *ad hoc* panel noted some areas that could be reinforced or expanded as listed below. Though these evaluations were based on expert observations, they need to be backed by objective metrics and a more thorough study of performance measures, as well as by evidence of progress that can be reasonably expected in those cases where performance seems to have fallen behind expectations. The panel chose to define some gaps and opportunities (discussed below) and not necessarily to give evidence for dropping programs.

In addition, on the basis of members' personal knowledge, but without an adequate review of all the existing BTRR centers, the evaluation committee noted some areas that may require strengthening, as well as some unevenness in the success of the Service, Training, and Dissemination components for some BTRRs. Rather than penalizing these programs, having an external panel advise the respective directors might carry more weight and precipitate more definitive action than the written review from ad hoc reviewers.

The evaluation panel notes that, although study section reviewers are familiar with the BTRR program, there is a disconnect in the review process between the study section and the Advisory Council. The evaluation committee proposes a Science Advisory Group to bridge the gap between the reviewers'/staff report and the advisory council. The group would be charged with a periodic evaluation of the existing program and its balance.

The panel also notes that during a competitive renewal, existing BTRR awardees compete against each other but do not compete against new BTRR applications. There is concern that this manner of competition hampers the emergence of novel science. The panel considered the possibility that the Advisory Council might welcome help in prioritization and selection of BTRR applications relative to NIH goals

Recommendation
An advisory panel should be created to assist council and NCRR leadership in the evaluation of the balance and the quality of BTRRs as well as how to achieve integration with the translational directions of NIH. The program-level committee should include extramural scientists, particularly those who were involved in the BTRR program in the past.

EXPANSION

The panel emphasizes the need to evaluate the NCRR budget so that the BTRR program can serve the anticipated needs of CTSA. Three areas of attention were discussed by the panel:

Systems Biology

The ultimate goal of systems biology involves the rapid generation of large analytical data sets (e.g. genomic, proteomic, metabolomic) and the integration and interpretation of complementary information to gain insight and ultimately predictive confidence about organism biology. This will likely be the core of translational science. Dissemination of mass spectrometry methodologies for proteomics and metabolomics and creation of informatics resources to translate the data from the analytical instruments to biology and clinical medicine were two unmet needs discussed in this evaluation. Although high-throughput generation of genomic data

has been possible for sometime, only recently have methods, mainly based on mass spectrometry, evolved for proteomics and metabolomics. These latter areas comprise arguably more difficult analyses because of the enormous structural complexity of both proteins (sequence, alternate splice products, PTM's, sensitivity required with no PCR equivalent, etc.) and metabolites (polarity, closely related structural classes, huge structural diversity).

New methods, which, unfortunately, NCRR has not been sufficiently involved in of late, are based mainly on high-throughput LC/MS/MS, leveraging enormous advances in high-speed chromatography coupled with fast scanning tandem and hybrid, high resolution/accurate mass (< 5 ppm) mass spectrometers. These instruments are now routinely providing **quantitative** protein sequencing information at the rate of about one protein per second at very high sensitivity, and include, for example, automated phosphorylation-site identification. Similar high-sensitivity, high-accuracy, and rapid throughput experiments are being conducted on thousands of metabolites analyzed simultaneously. For example, in the Stable Isotope Labeling of Cells in Culture (SILAC) experiment, such advanced systems, frequently in combination with stable isotope labels, allow time-course analysis of the phosphorylation states of thousands of proteins after signal transduction.

These incredible "Systems Biology" experiments are confined to a few laboratoriess that have the expertise. A major challenge for NCRR is to determine how to universally apply these methodologies through training at core centers. The cost of even the most advanced hardware technology from all vendors will rapidly come down because of competition, and many laboratories will be able to afford these systems. However, the risk is that they will not possess the expertise to apply the methodology effectively or accurately.

The next and closely associated problem is that these new systems generate so much high-quality data that analysis programs and informatics systems have lagged well behind, causing immense frustration for current users and a serious bottleneck in turning these data into translational medicine solutions. Again, this is an excellent opportunity for NCRR to take the lead in working with advanced laboratories, as well as with instrument vendors, by leveraging current accomplishments into informatics platforms for the future of systems biology and translational medicine. Opportunities exist for individualized medicine by complementing generic immunoassays with specific sequence differentiation from SNPs or alternative spicing. Other translational opportunities include protein patterns for sensitive biomarkers, drug discovery, and therapeutic monitoring.

Computational Informatics

Algorithm development and software tools are fundamental to making sense of the large amounts of data generated by new scientific hardware. This is critical to translational research programs, and thus these tools will be essential for the planned CTSAs. NIH is spending substantial money on such new hardware, but in many cases the data generated are so voluminous that they will become unmanageable because of a lack of appropriate software. New activities of the BTRR program should include Translational Software Development Resources (TSDR).

Modern scientific tools almost universally depend upon software to achieve the goals their designers foresaw. At the frontiers of science, software may be idiosyncratic, makeshift, and even unpredictable in the hands of any user other than the developer. Furthermore, the pace of change at the scientific frontier may force an investigator to use obsolete or ill-suited software rather than invest the time or money required to make the necessary modifications.

As with clinical and translational science, there is a pressing need for translational software development, which forms the missing link between an individual investigator's makeshift software suite and the transparency of a commercial software product. A TSDR would specialize in software for one kind of scientific tool. Computer scientists familiar with the relevant algorithms could analyze the original investigator's code, propose modifications where appropriate, and develop the code with proper modularity, structure, and documentation.

Several TSDRs, each focused on a different class of scientific tool, could accelerate the distribution of robust software to biomedical investigators nationwide. Much of the distributed software most likely would be open rather than closed source. Good software practices by the TSDR would encourage enduring improvements by users and result in rapid advancement of the scientific frontier. Although TSDRs would have to be subsidized, the total cost to the scientific community would be significantly reduced as a result of the increased sharing of code and the reduction of wasted hours and days spent by an investigator in understanding and debugging fragile software. The establishment by NCRR of a program to fund TSDRs within the BTRR program is well worth serious investigation.

Technology for Health Care

Engineering technology for health care is vital to improved care and a key aspect of the economics of health care. Focus areas include smart homes for the chronically ill, personalized monitoring devices, and improvement of hospital care through wireless devices. Whereas there is a clear need in this area that is not fulfilled by current Roadmap initiatives, the panel observed that this is not presently part of the NCRR mission but perhaps should be considered as a mandate for future translational approaches.

NIH TECHNOLOGICAL PROGRAM BALANCE

In the past 10 years NIH has embraced advanced technologies that have the potential to drastically alter our understanding of and cures for disease processes. The programs of other categorical ICs and the Roadmap initiatives are to some extent based on these technologies. As a result, categorical ICs sometimes see highly technological proposals that, though flawed, appear attractive to reviewers less familiar with technologies. Interactions with non-categorical ICs such as NIGMS and NCRR can aid categorical ICs in their evaluation of these technological proposals. The panel has no specific recommendation for the implementation of this interaction, but it notes its importance to ensure excellence in technology-oriented applications across all the ICs.

INTERACTIONS WITH INDUSTRY AND GOVERNMENT

The panel discussed what was known and what might be models for interactions between BTRR centers and industry, particularly with regard to intellectual property and shared financial and physical resources.

Do large companies such as GE, Siemens, Zeiss, and big pharma fund the work of the BTRR? In the experience of the panel and three center directors, interactions with large companies are not a *quid pro quo* culture, with only episodic investments in free instruments that in the final analysis are a drain on center budgets for installation and benefits. There are few if any records of enduring relationships with BTRRs (such as is the case between large corporations and radiology departments). Involvements are limited to discounts on equipment purchases and possibly some exclusive licensing agreements for developments enabled by manufacturers' new equipment.

The relationships among academic institutions, federal funding sources, and industry are increasingly important to discovery and dissemination of innovations and pre-competitive intellectual property. The advanced technologies developed, refined, and adopted through the BTRR program may be among our most important resources for strategic and efficient use of precious capital, multifaceted risk-taking, and ultimate commercial dissemination of discovery. Therefore, it is essential that these relationships be fostered in a thoughtful, quantitative, transparent and strategic manner to optimize potential return on scientific/intellectual opportunity. However, the panel notes the lack of information involving interactions among resources relative to private enterprises, local community, and state, federal, and international entities. To overcome this gap in knowledge, data-gathering methods are needed to inform the development of guidelines and advice to individual resources. Required information includes substantial commentaries on barriers imposed by local regulatory issues in specific transactions, as well as the articulation of local challenges including those imposed in state and federally operated facilities for the holding of equity, royalty distribution, and filing of patents. Several intellectual property and regulatory issues exist and vary from state to state for state institutions hosting BTRRs, as well as for private academic institutions. The development of a standard set of principles across states would be beneficial.

Recommendations

1. **The aforementioned Scientific Advisory Group should be broadened to include expertise in intellectual property (legal/ethical) and the greater issues of academic/government/industry partnerships.**
2. **Annual reports should include a quantitative description of industry joint ventures, partnerships, investments, shared equity, and specific problems encountered by resources relative to intellectual property.**

EVALUATION METRICS

The panel discussed the issue of measuring the performance of the overall BTRR program as well as that of the individual BTRRs. Generally, individual centers have been evaluated, based on the number of individual projects, publications, and advances generated. NCRR also has attempted to assess how these centers support investigators working on different research problems. The panel felt that the program staff and the Advisory Council should develop program-level metrics by which the BTRR program can be assessed on an ongoing basis. In

addition, there need to be performance metrics established for each BTRR at the time of the award, metrics that will be shared with the investigator so that there is transparency in the expectations for the Resource. It is expected that the individual Resource metrics would aggregate into the Program level metrics, which would help promote a strong alignment with expectations throughout the program.

The panel recognized the difficulty in establishing solid metrics across such a diverse collection of resources and also recognized that much of the information listed below is currently collected.

Metrics for overall, program-level success

- Patents
- Technology transfers
- Spin-offs and startups
- Papers and citations, including uniqueness and citation impact
- Leveraging of institute and foundation support, as well as that of NIH ICs (an example is the leverage of the P41 at the University of California, Irvine, in securing Beckman support)
- Training activities, including the success of trainees
- How the program supports clinical and translational research
- Evaluation of NCRR programs should align with evaluation of Roadmap results.

Metrics for individual Resource-level success

- Each of the Program-level metrics above apply to individual BTRRs
- A measure of user satisfaction and accessibility
- Overall scientific productivity in addition to uniqueness
- Quantification of service to medical science where applicable

At the time a Center is established, peer review plays a very important role in selection. Whereas the panel recognizes that programs do not have to score highly in all areas to be successful, it is their experience that site visitors do not understand the method of BTRR (P41) evaluations in all cases. For example, some technologies, such as synchrotrons, have been more service-oriented, but nevertheless remain a crucial part of the infrastructure supporting all disease research. BTRR programs based on such technologies thus would score highly in the Service component. The panel envisions that a metric for how well programs support clinical and translational research could be another area in which an application might distinguish itself.

Staff should expand the current written instructions (including the metrics for success if awarded) for conducting the evaluation of components of a Resource, recognizing that this evaluation will vary from center to center. Review committees consist of domain experts and generalists, but instructions and applications are usually written for domain experts only. Generalists might not understand the technical details of an application, but they can add valuable advice about the overall value of the Center.

Asking the program-level advisory panel to second guess a site-visit report seems unwise. However, having experienced staff provide an advisory panel and the Council with confidential written remarks about their perceptions of the competence of the review would, along with the study section report, help to achieve an objective decision in some of the problem reviews. The

Council would then have the expertise of the panel to advise them on the competence of the review and on technical issues relating to the importance of BTRR contributions, whether research, service, or collaboration. Neither the site visitors nor members of staff or council have the years of experience in BTRR activities that could be gained from the proposed advisory panel. Such a panel could be of major importance when translational research is viewed by some site visitors as really important, but not valued by other site visitors because of its lack of scientific innovation.

Recommendations

1. **Recognizing that the true impact of BTRRs is hidden in many inventions and collaborations, as well as in the training of successful medical scientists, nevertheless, the panel recommends that an effort be made to quantitate the accomplishments of the BTRR program since 1960, so that its continuing importance to NIH can be known. This activity can be an elaboration of the initial work staff has already presented.**
2. **The panel recommends that a separate section on scoring be included in the instructions to reviewers. This section should have an historical component, as well as a general discussion geared toward the non-specialist. This section also should make clear that a proposed program does not need to score highly in all areas to be successful. The instructions need to give guidance regarding the important value of support for translational activities.**

SUMMARY

A panel was convened to make an evaluation of the BTRR program of NCRR and to make recommendations regarding the need for and balance of that program. The panel consisted of ten scientists and engineers, all with many years of experience with NCRR and other NIH programs. The principal recommendations revolve around the importance of the BTRR program for facilitating translational research throughout NIH and specifically for the CTSA program. Recommendations include ideas for important new BTRR emphases, a new advisory panel, methods to attract new BTRR leaders, program and specific BTRR performance metrics, and mechanisms for gathering data to facilitate more effective BTRR/industry/government interactions.

PANEL COMPOSITION

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