

#### PERSPECTIVE ARTICLE

# US-National Institutes of Health-funded research for cutaneous wounds in 2012

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### **ABSTRACT**

Chronic cutaneous wounds are a major burden on patients, healthcare providers, and the US healthcare system. This study, carried out in part by the Wound Healing Society's Government Regulatory Committee, aimed to evaluate the current state of National Institutes of Health funding of cutaneous wound healing-related research projects. National Institutes of Health Research Portfolio Online Reporting Tools Expenditures & Results system was used to identify wound healing projects funded by the National Institutes of Health in the 2012 fiscal year. Research projects focusing on cutaneous wound prevention/education, mechanisms, complications, treatment, or imaging/monitoring were included in the analysis. Ninety-one projects were identified, totaling a collective funding of \$29,798,991 and median funding of \$308,941. Thirteen institutes/centers from the National Institutes of Health were responsible for awarding funds; three of which (National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of General Medical Sciences, National Institute of Diabetes and Digestive and Kidney Diseases) accounted for 60.4% of the grant funding. The predominant funding mechanisms included R01 (48.3%), R43 (14.3%), and R21 (9.9%). New applications and pre-existing applications accounted for 39.6 and 55.0% of the awarded grants, respectively. Grants awarded to investigators affiliated with universities accounted for 68.1% of grants and 25.3% were to investigators in the private sector. This analysis of current National Institutes of Health funding may facilitate more transparency of National Institutes of Health-allocated research funds and serve as an impetus to procure additional support for the field of wound healing.

Chronic wounds present a challenge to patients and health-care providers worldwide. In the United States alone, chronic wounds affect more than 6 million patients annually<sup>1,2</sup>, costing the healthcare system an estimated \$20–25 billion.<sup>3-6</sup> Patient care is often driven through basic, translational, and clinical research discovery, and while improved wound care has occurred, chronic wounds will become a more significant public health concern as the US population ages and the incidence of risk factors for chronic wounds such as diabetes mellitus continues to rise. Therefore, research and innovation in the understanding, prevention, and management of chronic wounds will be of critical importance.

The National Institutes of Health is the largest source of funding for biomedical research in the world; however, in recent years it has become increasingly difficult to obtain National Institutes of Health–sponsored funding.<sup>7-9</sup> In 2012, the National Institutes of Health had an overall success rate of funding only 18% of research grant applications, marking a sharp decline from 31% 10 years earlier.<sup>10</sup> Since the doubling

of its budget between 1998 and 2003, National Institutes of Health annual funding has remained nearly flat. This problem is further compounded by an increasing number of grant applications (63,524 in 2012) and concern over recent

FOA Funding Opportunity Announcement

NIAMS National Institute of Arthritis and Musculoskeletal and

Skin Diseases

NIDDK National Institute of Diabetes and Digestive and Kidney

Diseases

NIGMS National Institute of General Medical Sciences

NIH National Institutes of Health PA Program Announcement

RePORTER NIH Research Portfolio Online Reporting Tools Expendi-

tures & Results

RFA Request for Application WHS Wound Healing Society

reform of the National Institutes of Health peer review process. 11,12 Given the current economic landscape, a number of studies have raised the question of how and to which fields of medicine National Institutes of Health research funds are allocated. 13-17 The Wound Healing Society, the field's major research society, advocates for wound healing research funding. In part as members of the Wound Healing Society Government Regulatory Committee, we sought to examine the current distribution of National Institutes of Health funding for cutaneous wound healing projects in order to provide insight into funding allocation to better direct future research endeavors. We sought to capture National Institutes of Health funding for wound healing during the most recent fiscal year available.

#### **METHODS**

National Institutes of Health-funded research projects are searchable using the National Institutes of Health Research Portfolio Online Reporting Tools Expenditures & Results (RePORTER) system. This publicly accessible online tool provides comprehensive information for both intramural and extramural National Institutes of Health-funded research projects from 1989 to the present. This system was used to identify cutaneous wound healing projects funded by the National Institutes of Health in the 2012 fiscal year (October 2011–September 2012). Authors agreed on key terms and a search was performed using the key terms "wound," "wound healing," "chronic wound," "diabetic ulcer," "venous ulcer," "arterial ulcer," "burn," "skin ulcer," "skin regeneration," "sickle cell ulcer," "pressure ulcer," "scleroderma," "pyodermagangrenosum," "hyperbaric oxygen," "wound infection," and "cutaneous wound."

Project titles containing the word "wound," containing one or more key terms, or deemed related to the field of cutaneous wound healing were further screened for appropriateness. Two of the authors (NAR and RSK) independently reviewed each abstract of the selected projects. Research projects, in which the reviewers were in agreement, that focused on cutaneous wound prevention/education, mechanism, complications, treatment, or imaging/monitoring, were included in the analysis. We only included single projects and thus large multiproject or program grants were excluded. Exported data included administering institute or center, funding opportunity announcement (FOA), type, activity, support year, and fiscal year total cost. The authors determined the research categorization (basic, clinical, product/drug development) and organization type (university, private, veterans affairs, other). Additionally, annual National Institutes of Health funding of various medical conditions and disease conditions was extracted from the National Institutes of Health Categorical Spending list for comparison with funds allocated to wound healing.

### **RESULTS**

Of the 164 projects identified through the National Institutes of Health RePORTER key term search, 91 projects were relevant to wound healing for the 2012 fiscal year. Information regarding the grant value was available on 86 of the 91 projects, amounting to a total funding of \$29,798,991 and a median funding per project of \$308,941 (Table 1). Overall, 13

**Table 1.** 2012 National Institutes of Health funding of wound healing projects

2012 fiscal year funding	
Total funding	\$29,798,991
Median	\$308,941
Mean	\$346,500

institutes/centers from the National Institutes of Health were responsible for awarding funds; three of which (National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of General Medical Sciences, National Institute of Diabetes and Digestive and Kidney Diseases) accounted for 60.4% of the grant funding (Table 2).

All but three of the grants resulted from an FOA, of which 17% were solicited under a Request for Application and 83% a Program Announcement. Research project and career development/fellowship grants comprised 84.6 and 8.7% of the awards, respectively. The predominant funding mechanisms included R01 (48.3%), R43 (14.3%), and R21 (9.9%) (Table 3). New applications comprised 39.6% of awarded grants, while 55.0% were continuations of preexisting grants

Table 2. Wound healing grants awarded by an institute or center of the National Institutes of Health

Institute/center code	
NIAMS	24 (26.4%)
NIGMS	20 (22.0%)
NIDDK	11 (12.1%)
NIBIB	8 (8.8%)
NINR	7 (7.7%)
NHLBI	4 (4.4%)
NIAID	4 (4.4%)
VA	4 (4.4%)
NIA	2 (2.2%)
NIDCR	2 (2.2%)
NICHD	2 (2.2%)
NINDS	2 (2.2%)
AHRQ	1 (1.1%)

AHRQ, Agency for Healthcare Research and Quality; NIA, National Institute on Aging; NIAID, National Institute of Allergy and Infectious Diseases NIAMS, National Institute of Arthritis and Musculoskeletal and Skin Diseases; NIBIB, National Institute of Biomedical Imaging and Bioengineering; NICHD, National Institute of Child Health and Human Development; NIDCR, National Institute of Dental and Craniofacial Research; NHLBI, National Heart, Lung, and Blood Institute; NIDDK, National Institute of Diabetes and Digestive and Kidney Diseases; NIGMS, National Institute of General Medical Sciences; NINDS, National Institute of Neurological Disorders and Stroke; NINR, National Institute of Nursing Research; VA, Veterans Administration.

Table 3. Funding mechanisms of wound healing projects

Activity code	
R01	44 (48.4%)
R43	13 (14.3%)
R21	9 (9.9%)
R44	6 (6.6%)
101	4 (4.4%)
R03	3 (3.3%)
F32	2 (2.2%)
K01	2 (2.2%)
R00	1 (1.1%)
R24	1 (1.1%)
F31	1 (1.1%)
K08	1 (1.1%)
K24	1 (1.1%)
K99	1 (1.1%)
ZIA	1 (1.1%)
ZIC	1 (1.1%)

Table 4. National Institutes of Health support year

Support year	
1	36 (39.6%)
2–5	42 (46.2%)
6–10	9 (9.9%)
>10	4 (4.4%)

Table 5. National Institutes of Health application types

Application type	
New application	36 (39.6%)
Competing continuation	4 (4.4%)
Supplemental support	1 (1.1%)
Competing extension for an R37 award or first	1 (1.1%)
noncompeting year of a fast track award	
Noncompeting continuation	46 (50.6%)
Change of grantee institution	2 (2.2%)
Change of NIH awarding institute	1 (1.1%)

Tables 1–5 were derived using data from the NIH Research Portfolio Online Reporting Tools Expenditures & Results (RePORTER) system.

(4 competing, 46 noncompeting) (Table 4). The majority of projects were beyond their first year of National Institutes of Health support (60.4%); 46.1% were in support years 2–5, 9.9% were in years 6–10, and 4.4% were in support years >10 (Table 5).

When stratified by organization type, 68.1% of grants were awarded to principal investigators affiliated with universities

and 25.3% were to investigators in the private sector. The remaining grants were provided to the Department of Veterans Affairs or not-for-profit VA foundations, an institution, and a foundation. The majority of awards were provided to basic science/translational research projects (67.0%). Both clinical research and product/drug development projects were awarded 16.5% of grants. Common areas of research included diabetic ulcers or wounds (24.8%), wound prevention (8.8%), stem cell therapy (8.0%), and pressure ulcers (7.2%). Comparative National Institutes of Health funding allocations by disease category are listed in Table 6.

#### **DISCUSSION**

Despite the enormous economic burden of chronic wounds on the US healthcare system, the amount and allocation of National Institutes of Health funding directed toward research in this field are not well known. Through the use of the National Institutes of Health RePORTER database, 91 cutaneous wound research projects receiving funding during the 2012 fiscal year were identified, totaling \$29.8 million in funding. This implies that the total cutaneous wound healing research funding accounted for only 0.1% of the overall National Institutes of Health budget of \$30.69 billion. This value closely matches the total National Institutes of Health support of research on Lyme disease,18 a condition with an estimated annual cost of \$2 billion, 19 or one-tenth of that spent on caring for chronic wounds. Likewise, the National Institutes of Health estimates awarding \$32 and \$29 million during the 2012 fiscal year in support of two exceedingly rare genetic conditions, Duchenne/Becker muscular dystrophy and Fragile X syndrome. 18 This allocation discrepancy highlights the need for a more in-depth evaluation of the proportion of total funding distributed to various medical conditions.

Chronic cutaneous wounds are often complicated by serious adverse events and are associated with high rates of mortality. Diabetic foot ulcers are especially lethal, with

Table 6. National Institutes of Health categorical spending

National Institutes of Health categorical spending	FY 2011 (\$)	FY 2012 estimate (\$)
Lyme disease	28	28
Fragile X syndrome	29	29
Duchenne/Becker muscular dystrophy	32	32
Chronic obstructive pulmonary disease	108	108
Arthritis	231	228
Hypertension	240	241
Influenza	272	271
Alzheimer's disease	448	498
Diabetes mellitus (types 1 and 2)	1,076	1,079
HIV/AIDS	3,059	3,075
Cancer	5,448	5,451

Table 6 shows annual NIH support levels for various conditions and disease categories (NIH categorical spending).

mortality rates higher than many common cancers.<sup>20</sup> Patients with other chronic wounds such as venous leg ulcers and pressure ulcers have a higher risk of death than their agematched counterparts as well.<sup>21</sup> Furthermore, no new pharmacological treatments for chronic wounds have been approved by the Federal Drug Administration in over 10 years.<sup>22</sup> As these wounds continue to become more common, they will be difficult to manage with a treatment repertoire that does not expand at the same rate of the disease prevalence. Without funding to fuel the entrance of preventative measures or new therapeutic options, healthcare spending costs will continue to rise.

This study must be interpreted in the context of the study design. Many funded projects relevant to the advancement of cutaneous wound healing may not have been retrieved through our search methodology. Additionally, the National Institutes of Health RePORTER system does not provide data regarding unfunded grant submissions. Furthermore, we are unable to compare grant application success rates across specialties. Finally, there are no data regarding the outcomes of funded research projects or assessments of the impact of the research on the practice of the field.

Chronic wounds are a major public health concern, one that should demand greater support and transparency from the National Institutes of Health. The National Institutes of Health compiles annual funding data on 233 conditions/areas of research posted as categorical spending, of which wounds are not listed. We hope that this investigation promotes better documentation and categorization of grant application submissions and grant awards to promote improvement in funding distributions to wound healing research. We envision that this analysis of current National Institutes of Health funding could serve as a starting point for more in-depth evaluation of National Institutes of Health-supported wound healing projects.

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