Comparing Cutaneous Research Funded by the U.S. National Institutes of Health with the U.S. Skin Disease Burden

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ABSTRACT

Background: Disease burden should be an important component for guiding research funding.

Objective: To examine the relationship between dermatologic research funded from 2012-2013 by the National Institutes of Health (NIH) and U.S. skin disease burden as measured by disability adjusted life years (DALYs) in the Global Burden of Disease (GBD) 2010 study.

Methods: A cross-sectional analysis was independently performed by two researchers who matched projects from the 2012-2013 NIH Research Portfolio Online Reporting Tool with fifteen skin conditions and their respective DALYs from GBD 2010.

Results: The NIH funded 1,108 projects spanning the fifteen skin conditions. Melanoma received almost half of the total skin condition budget (49.5%). Melanoma, non-melanoma skin cancer (NMSC), and leprosy were funded above what would be suggested by their disease burden, while dermatitis, acne vulgaris, pruritus, urticaria, decubitus ulcer, fungal skin diseases, alopecia areata, cellulitis, and scabies appeared under-funded. Bacterial skin diseases, viral skin diseases, and psoriasis were well-matched with disease burden.

Limitations: Disease burden is one of many factors that may be used to guide priority-setting decisions.

Conclusion: Skin disease burden measured by DALY metrics partially correlates with NIH funding prioritization. Comparing U.S. disease burden with NIH funding suggests possible under- and over-funded skin diseases.

70 **Capsule Summary**

- 71 • Research funding is limited.
- 72 • National Institute of Health funding dollars for dermatologic conditions partially correlate
- 73 with respective skin disease burdens.
- 74 • Increased transparency and accountability of priority-setting processes for large national
- 75 research organizations will better allocate limited research dollars.
- 76

INTRODUCTION

The 2010 Global Burden of Disease Study (GBD 2010) quantified disease morbidity and mortality along with 1190 clinical sequelae and 67 risk factors for 291 diseases in 187 countries from 1990-2010. The study measured disease burden in disability-adjusted life years (DALYs) which combines years of life lost and years lived with disability such that one DALY equates to one lost year of healthy life.¹⁻⁴ GBD facilitates epidemiologic comparison of disease burden.^{5,6} Fifteen skin conditions are represented in the study along with a category for *other skin and subcutaneous diseases*.

Prior to GBD 2010, in 1998, the Institute of Medicine (IOM) urged the National Institutes of Health (NIH) to correlate burden of disease with U.S. funding distribution.⁷ Since this proposal, high mortality diseases, such as human immunodeficiency virus, have received far more money per death as compared to other diseases. Lobbying support also influenced research allocation, with every \$1,000 dollars spent on lobbying translating into \$25,000 more in research funding.⁸ Despite these changes, the IOM recommendations were not extensively implemented, as prior investigations have revealed that DALYs account for only 33% of NIH disease-specific funding in 2006.⁹⁻¹¹

As researchers pressure the NIH into representative funding allocation, scientists compete for limited resources.⁶ When adjusted for inflation, the 2013 NIH budget represents a 23% decrease compared to the pre-recession years in 2003.¹¹ Applications for research grants and training duration have also declined over the past several years, paralleling the state of NIH funding.¹² Tight allocation of resources ultimately has serious implications for the future direction of research.

The NIH RePORT Expenditures and Results (RePORTER) system is a public web-based tool with a repository of NIH-funded research. The online portfolio provides access to U.S.-based research abstracts and award amounts.¹³ Applicants submit applications for NIH funding, which must be approved by a Scientific Review Group (SRG) and subsequently approved by Institute and Center (IC) National Advisory Councils or Boards composed of both scientific and public representative experts.¹⁴ In 2012 and 2013, a total of 51,836 and 61,627 research grants were supported by the NIH with an average of \$492,012 and \$469,562 per grant, respectively.¹⁵ This study compares 2012-2013 NIH funding of skin-specific research with respective U.S. disease burden from GBD 2010 to explore the distribution of funding across dermatologic conditions.

METHODS

A cross-sectional analysis was performed comparing the DALYs of fifteen GBD 2010 skin conditions with corresponding total NIH grant funds awarded between 2012 and 2013. GBD 2010 collaborators selected fifteen skin conditions based on prevalence, common case definitions, and data availability: dermatitis, acne vulgaris, bacterial skin diseases (excluding leprosy), viral skin diseases, urticaria, fungal skin diseases, pruritus, scabies, alopecia areata, cellulitis, decubitus ulcer, melanoma, psoriasis, non-melanoma skin cancer (NMSC, composed of squamous and basal cell carcinoma), and leprosy. GBD 2010 also included a category for *other skin and subcutaneous diseases* (Table 1). Of note, the dermatitis category includes the following conditions: atopic dermatitis, seborrheic dermatitis, diaper dermatitis, allergic contact dermatitis, irritant contact dermatitis, unspecified contact dermatitis, exfoliative dermatitis, and dermatitis due to substances taken internally. Global disease burden is broken down into country-specific disease burden. Comparisons with U.S. NIH funding in this paper solely use U.S.-

specific GBD data. The methods used by the GBD project to generate disability estimates as well as GBD 2010 ICD-9 and -10 code disease definitions are published elsewhere.¹⁷⁻¹⁹ DALY metrics, expressed as percent of total U.S. DALYs of 291 conditions measured in GBD 2010, were obtained from the GBD Compare website.²⁰ Using this tool, search parameters of ‘time plot’, ‘DALYs metric’, ‘United States’ place, ‘all ages’, ‘both’ sexes, and ‘%’ units were selected.

NIH grants awarded in the U.S. in 2012 and 2013 were obtained online using the Research Portfolio Online Reporting Tool (RePORT) at <http://projectreporter.nih.gov/>. Within each ‘Query’ page, the Fiscal Year “2012” and “2013” were selected, “Projects” was selected under ‘Search In’, ‘Text Search (Logic)’ was changed to “Advanced” and ICD-10-determined search terms were strung with “OR” or “NOT” or “AND” as necessary.

Grant titles and abstracts were evaluated to determine a specified skin condition focus. Terms mentioned solely in “project terms”, “application”, or “public health relevance” were not used to guide categorization. As per GBD 2010 parameters, grants which focused on internal manifestations of systemic illnesses such as systemic lupus erythematosus and dermatomyositis were excluded. These conditions are included under the GBD 2010 category of “musculoskeletal diseases”. However, variants of cutaneous lupus—such as discoid lupus—were included in the GBD 2010 *other skin and subcutaneous diseases* category.

Broad scientific themes of skin grant proposals were grouped as basic science (animal subjects or non-animal subjects) or clinical research (subcategories: etiology, prevention, detection/diagnosis/treatment). Grants were also placed into several additional categories including: training programs, conferences, and Research/CORE center. If grants were assigned to more than one category, the full grant amount was counted in each individual category.

NIH funding for the fifteen skin diseases was subcategorized into a total of twenty associated funding U.S. NIH Institutes, Centers, and Offices (IC) (see eTable 1).²¹ If a “Funding IC” category was not listed on the exported excel document, the project title link was accessed, the “Details” tab was selected, and the “Administering Institutes or Centers” was used as “Funding IC”.

All data was extracted and categorized by two authors (EH and SP) in August 2014. The studies were cross-examined by each author, with consensus review by senior author (RPD) to resolve discrepancies. The number of grants and proportion of NIH funding for each skin condition were matched to the respective U.S. DALY metric.¹⁶ Matching was accomplished by creating a data plot of funding versus disability to generate a linear line of best fit with correlation coefficient, and qualitatively determining those conditions that were well-matched or poorly-matched (over- and -under-funded), compared to respective DALY metrics.

As this study did not involve human subjects, institutional review board approval was not necessary. Additional supplementary eTables listing all NIH funded cutaneous projects assigned to each skin condition are available by contacting the corresponding author.

RESULTS

During 2012-2013, the NIH supported 1,108 grants covering the fifteen skin conditions at a total of \$388 million, constituting 0.98% of total NIH issued grants and 0.77% of total NIH funding. Comparing DALY disability estimates to disease funding, melanoma, NMSC, and leprosy were over-funded (Table 1 and Figure 1). Dermatitis, acne vulgaris, pruritus, urticaria, decubitus ulcer, fungal skin diseases, alopecia area, cellulitis, and scabies were under-funded. Burden and funding appeared well-matched for bacterial skin diseases, viral skin diseases, and psoriasis.

Melanoma surpassed all of the skin diseases with the largest proportion of NIH skin disease funding and grants awarded (476 and 49.53% respectively). NMSC had the second highest funding (13.47% of funding, 194 NIH grants), followed by viral skin diseases (6.42% of funding, 68 NIH grants). Dermatitis represented the highest burden of disease but ranked fifth in dollar allocation with 5.22% of total funding.

Urticaria, the seventh most disabling condition, received the lowest amount of funding (0.29% of funding, 6 NIH grants). Similarly, acne vulgaris ranked fourth in disability but encompassed only 0.54% of total funding (11 grants), while leprosy, the lowest disease burden, ranked eighth of fifteen (3.18% of total funding, 26 grants). Infectious dermatologic conditions of bacterial (excluding leprosy) and viral skin diseases were well-matched (2.07% and 6.42% respectively). The *other skin and subcutaneous diseases* category included 45 total conditions, of which 15 were funded, and received the third highest NIH allocation (7.91%, 109 grants). Within the category, pemphigoid (ICD-10 code L12) disorder received the highest proportion of funding (37.76%).

When examining the NIH IC's funding, similar patterns were evident in the highest funded cutaneous diseases (Figure 2, eTable 1). The National Cancer Institute (NCI) was the highest funding institute contributing 78.94% of total NIH funding to melanoma (Figure 2). The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) contributed the second highest funding of \$64,329,536 to 202 projects across 13 skin conditions.

A diversity of scientific themes was represented amongst the skin conditions. Basic science received greater allocation than clinical research: detection/diagnosis/treatment research (56.4% and 15.3%, respectively, Table 2). Conferences received the lowest funding (0.04% of total funding, 15 grants). Fifty projects included both a basic science and clinical focus. Basic

science studies using animal models encompassed 24% of total funding allocation. Pruritus, *other skin and subcutaneous diseases*, and NMSC had the highest number of animal studies (57.9%, 41.8%, 38.8%, respectively, Table 3).

DISCUSSION

This study utilized burden of disease metrics from the open access GBD 2010 database to investigate prioritization of cutaneous research funded by the NIH. This epidemiologic data has the potential to inform priority-setting methods and impact policy-making. Countries around the world have established collaborations with the GBD Institute for Health Metrics and Evaluation to incorporate disease burden into policy discussions.²²

Nevertheless, there are important limitations of using GBD to inform or influence NIH spending. As a major U.S.-based research organization, the NIH may consider differences in U.S.-specific disease burden with global disease burden when setting research priorities. For example, melanoma causes significantly greater disease burden and mortality in developed regions such as North America and Europe, when compared to developing regions in Africa, Asia, and South America.²³ Melanoma NIH funding vastly exceeded all other skin conditions with almost half of total allocation and appeared over-funded when compared to disease burden. Although over 80% of malignant melanoma is diagnosed in early stages, patients with advanced disease utilize 34-55% of total cost and suffer tremendous distress.²⁴ There are only a handful of FDA-approved treatment options for metastatic melanoma, and many NIH studies focused on targeting biochemical pathways and novel therapeutic regimens.

The DALY metric for skin diseases only considers disability from the cutaneous aspect of each skin condition; it does include disability related to other organ systems. For example, decubitus ulcers caused by venous insufficiency cause significant morbidity beyond their

cutaneous disfigurement, including reduced ankle range of motion.²⁵ Alopecia areata has been linked to a strong autoimmune comorbidity, including hypothyroidism and diabetes mellitus, but these comorbidities were not factored into its rank.²⁶ Dermatitis is well-established with persistent loss of sleep cycle, intractable pruritus, stress, and impact on social interactions.²⁷⁻³¹ Thus, the GBD metric likely grossly underestimates the true burden from these skin conditions.

Lobbying by specific disease interest groups such as the Melanoma Research Foundation and National Psoriasis Foundation may contribute to increased allocations for certain diseases.^{32,33} Pharmaceutical companies and private corporations, such as the National Eczema Association (NEA) and The American Acne and Rosacea Society (AARS), also sponsor research projects.^{34,35} Therefore, many non-governmental agencies may be funding research on diseases that appear under-funded by the NIH.

The availability of treatment options for a particular disease may also impact research prioritization by the NIH. Conditions with validated and established therapies, even with high disease burden, may warrant less NIH funding dollars than conditions with moderate disease burden but lacking treatment options. A potential example is the over-funding of melanoma research and the under-funding of dermatitis research by the NIH when compared to GBD metrics. As already mentioned, dermatitis is responsible for the highest disease burden of the 15 skin conditions but ranked number 5 in NIH funding. A variety of well-established therapies are the standard of clinical practice for dermatitis, including emollients, topical corticosteroids, and topical calcineurin inhibitors.³⁶ In contrast, although melanoma is responsible for the third-greatest disease burden in the U.S., well-established therapies for the most morbid aspect of the disease, metastatic melanoma, are needed. Melanoma was allocated the greatest amount of NIH

funding dollars of the 15 skin conditions, and in recent years, novel therapies for metastatic melanoma have become a hot bed for research.³⁷

The NIH may prioritize lower burden disease areas that are on the verge of a breakthrough or that may effect change and overcome health inequalities.³⁸ For the 15 skin conditions, there was a greater proportion of clinical compared to basic science research. This is consistent with a recent decline in spending on basic science from 68.3% in 2004/2005 to 59.4% in 2009/2010.³⁹ It is postulated that this decline is due to retrospective analyses suggesting that clinical research has the most beneficial effect on patient care.⁴⁰ In addition, recent systemic reviews of animal studies propose that the design, quality, and relevance of animal studies are questionable.^{41,42} For example, a survey of 271 animal studies found only 12% report random allocation and only 14% of studies used blinded investigators.⁴¹

The NIH, along with other national funding bodies, has a duty to look forward to and anticipate priorities that will emerge in future years. Temporal change in DALY reveals important patterns in disease epidemiology that may guide priority-setting decisions. As an example, NMSC can cause an expected future burden as the U.S. population ages. The age-standardized DALY for NMSC increased 40% from 1990 to 2010, while melanoma decreased by 15% over the same time period.⁴³

Assigning each NIH project to a particular skin condition does not take into consideration that fundamental or clinical research on one disease may aid the understanding or treatment of other diseases. The relatively large amount of NIH funding for leprosy compared to its disease burden, highlights the use of *mycobacterium leprae* animal models to study cell-mediated

immunity to better understand immunoregulatory mechanisms of infection. This research has broad applications to bacterial, viral, and fungal skin diseases.^{7,44,45}

While the NIH issues funding announcement opportunities via requests for proposals (RFPs), these research endeavors are limited by the number of researchers working in each disease area. For example, urticaria, the most common dermatologic disorder in the emergency room, may be responsible for high disease burden, but has few researchers working on it.⁸ While many factors influence research prioritization, we suggest that burden of disease makes a good starting point for discussion.

Finally, the current study included an investigation of grants supported by the NIH only during the 2012-2013 fiscal years; thus, extrapolation of data to previous decades is limited. Assignment of a project to a particular disease category introduced some degree of subjectivity, although this was minimized through independent analyses by two study authors.

Future directions for the NIH may include adopting principles set forth by other organizations. The Patient-Centered Outcomes Research Institute (PCORI) operates under three goals: (1) increase the quantity, quality, and timeliness of comparative research; (2) accelerate implementation of research evidence; and (3) promote patient-centered research projects. Results that are patient-centered and likely to change clinical practice are given high priority; NIH goals lack both of these criteria.⁴⁶ The Health Technology Assessment (HTA) program in the United Kingdom also provides an exemplary priority-setting process. The HTA uses evidence via published systematic reviews linked to cost-effectiveness on a particular topic. In addition, recommendations from physicians and policymakers for commissioned research are thoroughly analyzed. The HTA operates on a fine balance between commissioner-led and researcher-led

projects, all the while accounting for cost-effectiveness and public health relevance.⁴⁷ While a variety of models and factors contribute to research prioritization, increasing transparency of any priority-setting process is important to ensure proper allocation of limited research dollars.

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FIGURE LEGENDS

Figure 1. National Institutes of Health skin funding compared to Global Burden of Disease

Study 2010 disability-adjusted life year estimates. This is a scatter plot of the percent of National Institutes of Health skin funding from 2012-2013 compared to percent of total disability-adjusted life year estimates for skin diseases from the Global Burden of Disease Study 2010.

Figure 2. National Institutes of Health and Centers funding by cutaneous disease. This figure depicts the divisions of the National Institutes of Health that are providing funding for each respective skin disease.

Footnote: NIDCR=National Institute of Dental and Craniofacial Research; NCCAM= National Center for Complementary and Alternative Medicine

Figure 1

Figure 2

Table 1. Categorization of NIH grants, funding, and US Global Burden of Disease DALY metrics (arranged in order of decreasing US DALY)

Category	ICD-10 codes populating disease category in GBD 2010 ¹	Funding ² (Percent) ³	Number of NIH grants in 2012 and 2013	US DALY ⁴ 2010 Absolute Number ⁵ (Percent of total DALYs of all GBD conditions)	US DALY 2010 Skin Disease Rank ⁶	NIH Funding 2012-2013 Rank
Dermatitis including eczema	L20-L27 ⁷	\$20,209,950.00 (5.22)	53	390,233 (0.48)	1	5
Non-melanoma skin cancer	C44, D04	\$52,197,220.00 (13.47)	194	230,918 (0.28)	2	2
Melanoma	C43, D03, D48.5	\$191,877,157.00 (49.53)	476	220,168 (0.27)	3	1
Acne vulgaris	L70	\$2,082,980.00 (0.54)	11	205,356 (0.25)	4	14
Pruritus	L29	\$17,594,004.00 (4.54)	48	134,569 (0.16)	5	6
Viral skin disease	B00, B07-B09	\$24,886,829.00 (6.42)	68	116,972 (0.15)	6	4
Urticaria	L50	\$1,138,226.00	6	108,983	7	15

¹ See reference 11.

² For fiscal year 2012 and 2013, includes total cost by IC and total cost (sub projects).

³ Total funding for all NIH skin categories is \$397,466,551.00.

⁴ All ages.

⁵ Rounded to nearest integer.

⁶ Out of 15 disease categories studied by GBD 2010.

⁷ L28 excluded from this category, kept in "other skin and subcutaneous disease" category.

		(0.29)		(0.14)		
Decubitus ulcer	L89	\$3,982,251.00 (1.03)	14	84,763 (0.1)	8	11
Fungal skin diseases	B35, B36.0, B36.1, B36.2, B36.3, B36.8, B36.9	\$3,995,582.00 (1.03)	11	70,655 (0.086)	9	10
Psoriasis	L40-L41	\$12,838,552.00 (3.31)	50	64,342 (0.078)	10	7
Alopecia areata	L63.0, L63.1, L63.8, L63.9	\$2,127,599.00 (0.55)	8	58,662 (0.071)	11	13
Cellulitis	L03.0, L03.1, L03.2- L03.9	\$2,738,655.00 (0.71)	6	46,772 (0.057)	12	12
Abscess, Impetigo, and other bacterial skin diseases	L00, L01, L02, L04, L08, L88, L97, L98.0- L98.4	\$8,030,987.00 (2.07)	26	42,745 (0.054)	13	9
Scabies	B66	\$708,100.00 (0.18)	2	24,109 (0.029)	14	16
Leprosy	A30, B92	\$12,340,450.00(3.1	26	2.77 (0.000003	15	8

		8)		4)		
Other skin and subcutaneous diseases	B85, B87, B88, L05.0, L05.9, L10-L13, L28, L30, L42-L44, L51, L52-L53, L55-L60, L64-L68, L71-L75, L80-L85, L87, L90-L92, L93, L94-L95	\$30,662,580.00 (7.91)	109	240,645 (0.29)	N/A ⁸	3

⁸ N/A = not available.

Table 2. Broad Scientific Themes of NIH funded Skin Grants from 2012-2013

Category	Number of Grants	Percent of Total Skin Funding
Basic Science (non-animal)	376	32.4
Basic Science (animal)	315	24.0
Clinical: Detection, Diagnosis, and Treatment	159	15.3
Clinical: Etiology	74	9.5
Clinical: Prevention	54	4.5
Basic Science and Clinical: Detection, Diagnosis, and Treatment	22	3.1
Basic Science and Clinical: Etiology	15	.98
Basic Science and Clinical: Prevention	13	.98
Conference	15	.04
CORE Center	30	5.5
Training Program	35	3.6

Table 3

Table 3. NIH funding (2012-2013) for Animal vs. Non-Animal Studies by Skin Condition (arranged in order of decreasing DALY)

Disease Category	Number of Animal Studies	Percent of Total Disease Funding	Rank (Total funding percent)
Dermatitis including eczema	14	35.4	4
Non-melanoma skin cancer	79	38.8	3
Melanoma	106	21.8	6
Acne vulgaris	3	21.3	8
Pruritus	29	57.9	1
Viral skin disease	12	13.1	12
Urticaria	0	0	-
Decubitus ulcer	3	14.5	10
Fungal skin diseases	0	0	-
Psoriasis	11	21.7	7
Alopecia areata	2	34.9	5
Cellulitis	0	0	-
Abscess, Impetigo, and other bacterial skin diseases	5	17.7	9
Scabies	0	0	-
Leprosy	2	13.2	11
Other skin and subcutaneous diseases	54	41.8	2