

Priorities for Treatment and Services Established by the Combating Autism Act: Costs and Outcomes

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Background & Objectives

Created in response to growing concerns about ASD's prevalence and impact, the 2006 Combating Autism Act or CAA is the most ambitious ASD national research strategy to date. CAA mandated the InterAgency Autism Coordinating Committee or IACC to set priorities for federal research funding. Between 2008 & 2013, IACC monitored the allocation of \$1.8 billion towards these priorities, with more than \$1 billion from the US National Institutes of Health or NIH alone (Office of Autism Research Coordination, 2017).

Researchers and advocates have begun to question NIH's traditional emphasis on basic health science relative to intervention, and the extent to which this emphasis has translated into improved outcomes for the population of people with ASD. To date, only a handful of independent researchers have sought to systematically reconsider IACC's priorities and potential impact.

Objectives:

- To establish how many NIH-funded projects funded between 2008 and 2013 to address treatment and services for people with ASD sought to directly improve community-based services, close gaps for underserved groups, or build overall system capacity.
- To explore possible reasons for the lack of projects addressing immediate implementation in community settings, beginning with the clinical training and the experience of project leaders with regards to community-based services.

Methods

ARD Database searches

We utilized the Autism Research Database or ARD to identify projects undertaken by NIH and focused on ASD treatment, intervention, or services. ARD was created and is managed by the Office of Autism Research Coordination or OARC. OARC was created to support the activities of the IACC. ARD is organized around the principle questions identified by the IACC as part of their strategic plan (Office of Autism Research Coordination, 2017). ARD assembles a range of information (project title, principal investigator or PI, abstract, funding agency, funding amount, federal application ID). These data are freely available for download (for 2013 data, click [here](#)).

The different sources of funding for ASD projects were assessed in a first phase, through a series of steps that relied initially on broad categories captured in ARD. These are described below, and summarized in Figure 2. In this initial phase, we focused on the funds dispensed. Subsequent stages also include information on the number and types of projects funded, and the characteristics of principal investigators.

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1. *Federal*: We identified all projects within ARD that were funded by the federal government, as distinguished from private sources like the Simons Foundation and Autism Speaks.
2. *DHS*: We identified the subset of federal projects and funding initiated by Department of Health and Human Services or DHS. Other federal agencies that initiated a significant number of ASD projects captured in ARD include the Department of Defense, and the Department of Education.
3. *NIH*: We identified the subset of DHS projects and funding captured by ARD and initiated by the NIH, one of the most important divisions within DHS. Other divisions within the DHS that initiated ASD projects captured in the ARD include the Administration for Community Living, the Administration for Children and Families, the Agency for Healthcare Research and Policy, the Centers for Disease Control and Prevention, the Center for Medicare and Medicaid Services, and the Health Services and Resources Administration..
4. *Projects categorized under ASD treatment, intervention, or services*: We identified ASD projects undertaken by the NIH that were categorized in ARD under Question 4 (Treatment and Intervention) or Question 5 (Services) on the IACC's Strategic Plan.

Defining implementation

Dimensions of implementation. Implementation here is defined as the use of *clinical tools* to target *clinical outcomes* for a *clinical population* in a *community setting*. Each italicized term is described in greater detail below. In general, these definitions draw on a level of detail not always available in the materials published by researchers, and sometimes rely on the judgment and experience of the reviewer. In many cases, these details are intended to exclude initial research studies that might yield findings with implications for assessment or treatment, from studies of tools or techniques could be ready for immediate use by community-based professionals, where training and funding made available.

The use of the term **clinical** throughout does not restrict these definitions to medical settings, methods, or professionals. It is intended to encompass any specialized assessment or intervention activities delivered by, or under the supervision of, any specially trained professional, including those in medical, education, or community settings.

A **community setting** is one that is typically mandated to provide day-to-day assessment or treatment of ASD. This includes schools, outpatient clinics, community-based behavioral health program, and so on. This also includes any training provided to parents, and services provided in the person's home. It does not include specialized, university-based clinics, or more specialized programs not typically available through regional children's hospitals. This distinction is intended to exclude a specialized assessment or treatment program only available through a given children's hospital because of the hospital's role in developing a given research protocol. In such cases, the specialized assessment or treatment program is unlikely to be immediately accessible to other hospital or community settings, even with training and funding. One exception would be routine ASD diagnosis and assessment, using established and widely available tools, which is commonly available at most children's hospitals.

A **clinical tool** is a specific test, drug, intervention method, or program of services that could be used by a professional in a community setting for purposes of assessment or treatment. This tool is a recognized method for which training might be reasonably obtained through initial

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licensure, workshops, direct consultation, or materials accessible to the community-based clinician or educator. In many cases, information about the validity, reliability, and likely outcomes have already been published. This definition is intended to exclude a preliminary research finding only indicating a possible relationship between some outcome, and some independent variable suggestive of an intervention. This definition also excludes a method under development and has yet to be validated. In both such cases, the tool is not reasonably likely to be used with a reasonable level of fidelity by a professional in a community setting.

A **clinical population** is a group of individuals who have been diagnosed with a condition that merits treatment by a professional. This definition is intended to exclude research focusing on participants identified with characteristics of ASD or a related condition, but yet to be formally diagnosed. The exception would be for research exploring the use of a tool to screen for or diagnose ASD.

A **clinical outcome** is a skill or behavior that may realistically be the target of a program of assessment or treatment delivered by a professional. This definition is intended to exclude a preliminary research study first exploring a relationship between an intervention and a very specific characteristic that might not be the target of treatment.

Implementation coding

Coding for Levels of Implementation is summarized in Figure 1. The levels of primary interest to the present study are those relevant to immediate implementation in community settings (e.g., Level III). These codes were intended to capture projects focused on delivering services in community settings, closing gaps for underserved populations, and increasing system capacity. The Pre-Implementation level was intended to capture tools or techniques that might eventually be used in community settings, because they piloted clinical tools with clinical populations in more specialized settings. Within some of these codes, we also distinguished between those projects that assessed clinical tools, and those projects that actually tested their delivery. All other projects were coded as contributing to basic science, including those focused on research infrastructure or the training of researchers. The order of codes was intended to capture increasing level of relevance to large-scale implementation. If a project fell clearly within two codes, we assigned the higher code.

Phase 1 Coding of IACC subcategories for community implementation

We first applied supplemental codes to the IACC subcategories adopted by ARD related to Questions 4 (Treatments) and 5 (Services). These subcategories were derived from the IACC Strategic Plan, and summarized in the 2012-2013 Portfolio Analyses (see Office of Autism Research Coordination, 2017, pp. 52-67). Twelve specific subcategories were identified by the IACC within Question 4, and 9 specific subcategories were identified within Question 5. An “Other” subcategory within Question 4 and within Question 5 covers projects generally relevant to the broader question of Treatments and Services respectively, but which could not be assigned to any of the identified subcategories.

Phase 2 Coding of individual projects for community implementation

In Phase 2, we conducted reviews of the abstracts of individual projects within those subcategories immediately or eventually relevant to implementation (e.g., Levels II and III). At the time of writing, abstracts were not easily downloaded from ARD, and so we first downloaded relevant files from NIH REPorter (ARD has since expanded the information

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downloadable in a single file). The NIH REporter tools provide access to files containing more detailed information about NIH grants, including project abstracts and the publications resulting from these projects, as well as the unique identifiers needed to link this information to projects captured in ARD.

Coding project abstracts. These individual project reviews focused on any text in the abstract indicating: (a) the primary or secondary hypotheses, aims, or goals of the study, or (b) the long-term implications of relevance to public health. We also coded long-term implications and implications for public health using the same system for coding level of implementation described above.

We also scanned the titles of other projects within the “Other” subcategories for Questions 4 and 5, to identify projects with the potential to be immediately or eventually relevant to community implementation. If so, the abstracts of these projects were also reviewed in the same manner as described above. The goal here was to identify the subset of projects that were clearly and immediately relevant to implementation to subject to the review outlined above.

Background of PIs. To explore factors that might explain a relative lack of projects focused on community implementation, we began by considering the related clinical training and community experience of PIs of projects aiming to improve implementation. We selected all of the projects with specific aims or presumed long-term relevance for eventual implementation (e.g., Levels II and III) as identified in the previous step. We downloaded the resumes of PIs through Google® searches. For evidence of clinical training, we scanned resumes for information indicating the completion of a clinical degree and/or licensure in a recognized field of medicine, allied health sciences (e.g., psychology, speech-language pathology, occupational therapy, and so on), or education. For evidence of significant experience in community settings, we scanned resumes for information indicating at least 5 years of work after the completion of all requirements for licensure, delivering relevant services in a community setting, as defined earlier. We also considered evidence indicating experience leading community-based programs of services. Resumes that included a clear timeline of education and work history for at least the past 10 years were retained for coding.

Results

Review of sources for funding ASD projects

A review of projects listed in ARD revealed 6916 projects funded for \$1,886,048,017 between 2008 and 2013 (see Figure 2).

1. *Federal Sources:* \$1,444,950,169, or 77% of all ASD project funding came from federal sources. Private sources accounted for \$441,097,848 or 23% of all ASD project funding. Almost all of this private funding came through the Simons Foundation (\$305,632,750 or 16% of total funding) and Autism Speaks (\$119,218,935 or 6% of total funding).
2. *DHS:* \$1,265,842,089, or 88% of all federal funding for ASD projects was provided through DHS. DHS was responsible for 67% of all funding captured in the ARD database. Other federal agencies providing significant ASD project funding included the Department of Education (\$122,062,861 or 6% of total funding), the Department of Defense (\$32,088,323 or 2% of total funding), and the National Science Foundation (\$22,539,916 or 1% of total funding).

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3. *NIH*: \$1,067,409,700, or 84% of all DHS funding for ASD projects was provided through NIH. NIH was responsible for 57% of all funding captured in the ARD database. Other DHS entities providing significant ASD project funding included the Centers for Disease Control (\$106,587,127 or 6% of total funding), the Health Services and Resources Administration (\$84,044,185 or 4% of total funding), and the Agency for Healthcare Research and Quality (\$3,763,606 or less than 1% of total funding).
4. *Projects categorized under ASD Treatment and Services*: \$218,199,489, or 21% of all NIH funding for ASD projects was categorized in the ARD under Questions 4 (Treatment) and 5 (Services). This funding was directed through a total of 244 distinct projects. The other questions meriting the most significant level of funding from NIH clearly involved Basic Science, and addressed the biology (\$349,483,470, or 33% of all NIH funding) and risk factors (\$232,811,921, or 22% of all NIH funding) associated with ASD.

Comparing subcategory funding for NIH versus other agencies. We also summarized the relative emphasis placed on different subcategories by the NIH and by other agencies. With respect to Treatments, the funding dedicated by the NIH relative to the total (19%) was comparable to that of all other agencies combined (21%) (see Figure 3). More than one-half of all funding for treatment was spent by the NIH. Compared to other agencies, the NIH placed relatively greater emphasis on model systems and on randomized controlled trials derived from biological signatures, and relatively less emphasis on randomized controlled trials for early intervention.

With respect to Services, the funding dedicated by the NIH relative to the total (2%) was much less than that of all other agencies combined (15%) (see Figure 4). All other agencies combined spent almost 6 times more money on services compared to the NIH. Compared to other agencies, the NIH placed relatively greater emphasis on the impact of access on families and on treatments in diverse settings, and relatively less emphasis on evaluating training.

Phase 1 Coding of IACC subcategories for implementation

Coding of IACC subcategories for implementation is summarized in Figure 5. Most of the subcategories involving treatments centered on piloting tools in specialized settings, while most of the subcategories involving services centered on implementation in community settings.

We also summarized the level of NIH funding for subcategories of projects by level of implementation (see Figure 6). Most NIH funding evaluated in this first phase appeared to be dedicated to either piloting tools for implementation (55%) or Basic Science (36%). This was relatively greater than that noted for all other agencies, which spent a total of 61% of funding on these kinds of questions. Only 9% (\$20,759,757) of NIH funding for treatments or services appeared to be dedicated to improving implementation in community settings, with most of this dedicated to improving community-based delivery. This represents 2% of total NIH expenditures. In contrast, all other agencies appeared to spend a relatively greater proportion of funds for treatments or services (39%, or \$116,756,483) to improving implementation in community settings. This represents 14% of total expenditures for all other agencies combined.

Phase 2 Coding of individual projects for implementation

Coding of individual project abstracts and the background of Project PIs is summarized in Figure 7.

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Coding project abstracts. A total of 166 project abstracts were reviewed - i.e., abstracts from all IACC subcategories from Question 4 and Question 5 except those categorized as Basic Science. A total of 37 projects were identified with project aims involving implementation of community-based services. The cumulative cost of about \$36 million was substantially higher than suggested by the original coding of subcategories, though this still only represented about 3% of total NIH funding. About one-half of projects from subcategories indicating community implementation were not retained, usually because review of individual project abstracts revealed that they involved piloting tools or developing training curricula. About 1 out of 5 projects originally categorized as involving specialized implementation were reclassified as involving community implementation, most often because a review of the project abstract indicated a focus on parent training.

Coding the background of PIs. A Google[®] search for the resumes of all PIs of projects that (a) included specific aims or cited public health relevance, and (b) involved treatment in specialized or community-based settings, yielded 46 resumes. Review of these resumes indicated that the majority (27 PIs, or 59%) were clinically trained, almost always as psychologists or physicians. None of these PIs had significant experience delivering services in community-based programs, let alone leading such programs. The psychologists identified appeared to have all moved directly into faculty positions, sometimes after a brief tenure as a psychologist or postdoctoral fellow on a research project. The physicians identified were more likely to have significant clinical experience, although this appeared to only occur within specialized children's hospitals.

Results and Conclusions

These analyses indicate that relatively few of the projects funded by the NIH between 2008 and 2013 seemed likely to test a specific and immediately applicable tool or approach to improving ASD treatment or services in the community. A systematic review of individual project abstracts originally categorized by ARD as addressing ASD treatment or services revealed that only 17% of the funds spent to improve treatments and services actually addressed ASD intervention outside of specialized university and hospital settings. This represented a negligible proportion of overall NIH funding.

This gap is striking given that such services are universally recognized as the best means to improve the lives of people living with ASD in the near term. The paucity of research addressing service gaps and barriers severely limits the impact of all other research on treatment: even the most powerful intervention will have little impact if effective community-based services cannot be developed, gaps in reaching underserved groups cannot be closed, and barriers to building capacity cannot be overcome.

These analyses reveal that much more funding was spent by NIH on projects that piloted tools in specialized settings, and on basic research. Indeed, these findings shed new light on NIH's heavy emphasis on basic science; during this period, it dedicated 55% of funds towards the biology (Q. 2) and causes (Q. 3) of ASD, and up to an additional 24% towards research training and infrastructure (Q.7). In other words, almost 4/5s of all funding appears to have been dedicated to projects addressing questions of basic science, or supporting the infrastructure needed to ask such questions. Additional reviews of a sample of individual project titles and abstracts, as conducted here on projects in the Other subcategory, will be helpful in confirming these trends.

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Further research will be needed to elucidate possible reasons for the scarcity of projects addressing community implementation of treatment and services. The present analysis suggests that this disinterest may stem from the absence of significant community experience among the PIs reviewed. Such experience can sensitize clinical researchers to the urgency of the need, as well as to specific strategies to close these gaps. PIs who are not clinically trained will always struggle, however, to understand the complexities of delivering treatment effectively, let alone closing the gap in community implementation. Additional research characterizing the background of all members of the research team may reveal other contributors who can draw on significant community experience.

Additional research may confirm and extend these findings in other important ways. The review of individual project abstracts revealed that the reliance on broad subcategories is inadequate to capture details about the specific aims and presumed relevance of the project. To confirm these trends, abstracts from other subcategories may need to be sampled to evaluate if other projects addressing implementation in community settings are being missed. It is also important to recognize that important project details can never be gleaned from these abstracts alone. By reviewing the resulting publications, for example, we can verify whether the resulting study addressed community implementation. This might allow us to explore whether the findings themselves are likely to impact actual community practice, based on a review of the number, type, and quality of recommendations.

References

Office of Autism Research Coordination. (2017). 2013 he review of individual project abstracts IACC Autism Spectrum Disorder Research Portfolio Analysis Report. Retrieved from <https://iacc.hhs.gov/portfolio-analysis/>

For further information about this project, please contact
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Figure 1: Coding for levels of Implementation

Terms that are underlined are the specific codes used in the present study

I. BASIC SCIENCE AND TOOL DEVELOPMENT

- 1) *Basic science and other programs*: The project clearly focuses on causes, characteristics, developmental changes, and so on. This includes: (a) intervention research that does not focus on *clinical outcomes* typically and directly targeted by practitioners; for example, changes in a behavior not typically targeted in clinical settings or whose significance to date has yet to be established, or measures only used in research projects. (b) Infrastructure for basic science, or; (c) Programs to train researchers
- 2) *Development of tools and techniques*: In all cases, the project must address clinical outcomes as defined above. This includes: (a) developing assessment or treatment tools or platforms but without any actual testing of the tool with a clinical population; (b) developing training curricula or software associated with delivering services, or (c) work needed to prepare for a clinical trial.

II. PRE-IMPLEMENTATION IN SPECIALIZED SETTINGS

The project involves the use of specific and clearly defined clinical tools or techniques in *specialized settings* (e.g., a research clinic or a specialized hospital) on a *clinical population* (actually or potentially diagnosed with ASD or a related condition). These tools and techniques are considered to be eventually relevant to implementation. The setting is presumed to be specialized unless otherwise specified.

- 1) Pilot tools: The project pilots or seeks preliminary validation of a clinical tool or technique prior to implementation. This includes initial clinical trials, or projects exploring the moderating or mediating effect on a clinical target for a clinical technique. Validation of tools for parent training is coded here.
- 2) Specialized delivery: The project uses an validated clinical tool or technique in a specialized setting. The project may include extending the validation of a clinical tool or technique in a specialized setting. Parent training is always considered to involved implementation in community settings, and is coded below..

III. IMMEDIATE IMPLEMENTATION IN COMMUNITY SETTINGS

The project involves the use of a validated clinical tool or technique to address a clinical outcome on a clinical population, as defined above. *Community settings* include schools, the home, the workplace, and general hospital, an outpatient clinic, and so on. Any form of parent training is automatically included here.

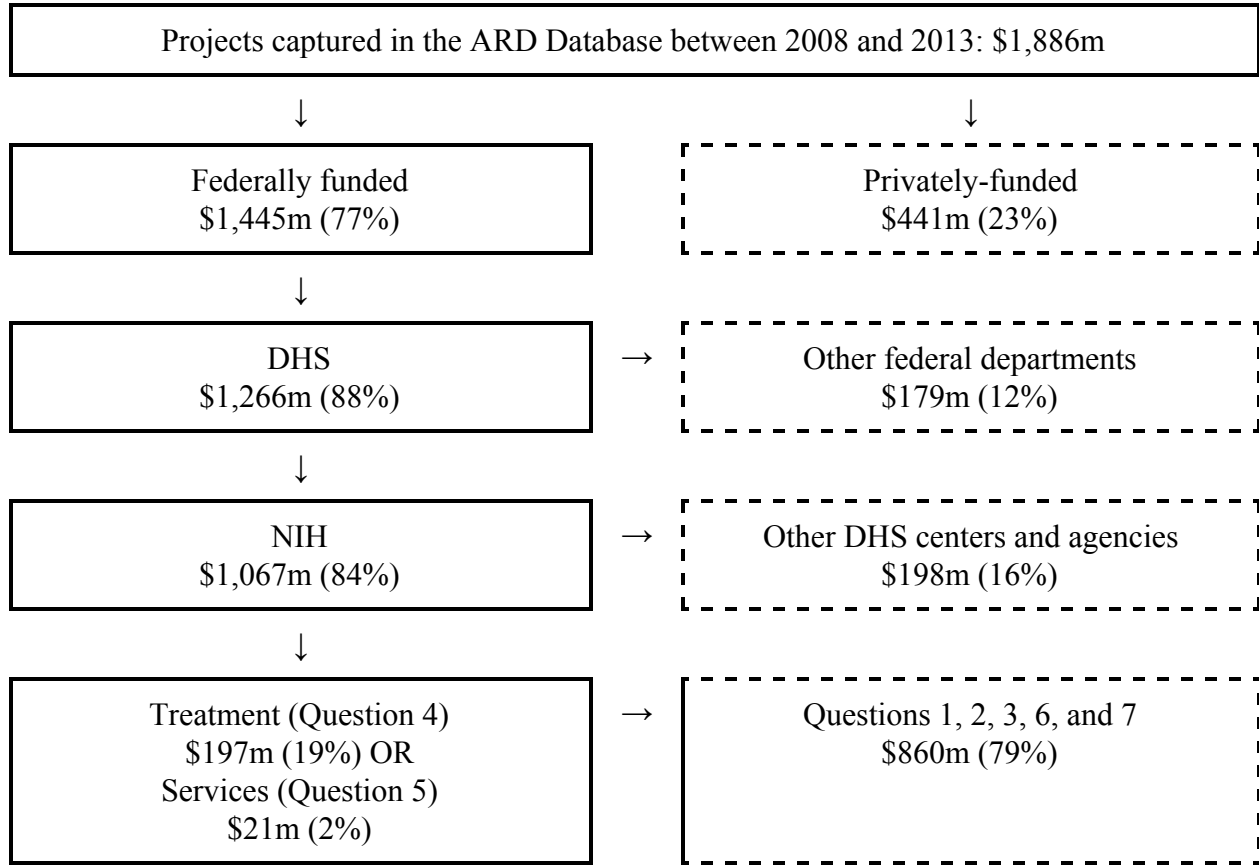
- 1) Delivering services. This includes:
 - a) Assessing delivery: The project assesses the use of a clinical tool or technique. This can include the first use of a new tool or technique in a community setting for the purpose of establishing its delivery. The project does not itself need to result in the delivery of a tool or technique; it can survey its delivery.
 - b) Improving delivery: The project involves the delivery of a tool or technique, with the goal of improving its use. This includes the modification of a tool already in use in the community.

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- 2) Closing gaps for underserved populations (e.g., those with less education or income, or from minority groups) in community settings. This includes:
 - a) Assessing access: The project assesses access to a clinical tool or technique for an underserved population. The project does not itself need to result in the delivery of a tool or technique; it can survey gaps in its delivery.
 - b) Improving access: The project seeks to improve access to a clinical tool or technique for an underserved population.
- 3) Building system capacity The project explicitly addresses the capacity to deliver a tool or technique through improved training, funding, policy, and programs. This includes:
 - a) Assessing capacity: The project seeks to assess system capacity This includes large scale studies seeking to establish the number of children diagnosed or treated
 - b) Building capacity: The project seeks to demonstrate how to increase system capacity

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Figure 2: Decision Tree for the selection of project subcategories directly relevant to Treatment (Q.4) or Services (Q. 5) in Phase 1 (millions of dollars)



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Figure 3: Funding of subcategories of projects focused on Treatment (Question 4) for 2008 to 2013, for NIH relative to other agencies

<u>Subcategory</u>	Funds allocated (% of total for Q. 4)	
	NIH	All Other Agencies
4.S.A RCT for co-occurring conditions	\$1,321,638 (1%)	\$17,471,420 (10%)
4.S.B Model Systems	\$71,290,717 (36%)	\$45,164,826 (26%)
4.S.C Efficacy of common interventions	\$4,697,421 (2%)	\$6,112,725 (4%)
4.S.D RCT of EI	\$22,959,536 (12%)	\$29,555,813 (17%)
4.S.E Workshop on Subtypes	\$0	\$31,000 (<1%)
4.S.F RCTs derived from biological signatures	\$30,347,660 (15%)	\$14,565,107 (8%)
4.S.G Interventions for non-verbal individuals	\$10,859,393 (6%)	\$2,775,635 (2%)
4.S.H Prevention of secondary conditions	\$1,929,472 (1%)	\$199,975 (<1%)
4.L.A RCT on medications for core symptoms	\$10,859,842 (6%)	\$3,044,491 (2%)
4.L.B Interventions for siblings	\$976,173 (1%)	\$204,532 (<1%)
4.L.C Medications for co-occurring conditions	\$6,088,242 (3%)	\$1,052,846 (1%)
4.L.D Community-Based Interventions	\$6,084,070 (3%)	\$30,900,598 (18%)
4.O. Other Questions	\$29,651,084 (15%)	\$20,386,523 (12%)
Total for question 4	\$197,065,248. (19%)	\$171,465,492 (21%)

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Figure 4: Funding of subcategories of projects focused on Services (Question 5) for 2008 to 2013, for NIH relative to other agencies

<u>Subcategory</u>	Funds allocated (% of total for Q. 5)	
	NIH	All Other Agencies
5.S.A Impact of access on families	\$3,741,946 (18%)	\$2,995,444 (2%)
5.S.B Self-Directed services	\$330,752 (2%)	\$407,223 (<1%)
5.S.C Model state coordination	\$ (0%)	\$5,465,315 (4%)
5.S.D Health and Mortality	\$100,000 (<1%)	\$64,135 (<1%)
5.L.A Treatments in diverse settings	\$8,223,949 (39%)	\$27,092,247 (22%)
5.L.B Effectiveness of community services	\$0	\$1,086,166 (1%)
5.L.C Evaluate training	\$1,218,104 (6%)	\$48,087,657 (38%)
5.L.D Health and self-determination	\$59,998 (<1%)	\$571,840 (<1%)
5.L.E Dental Services	\$1,100,938 (5%)	\$131,992 (<1%)
5.O. Other Questions	\$6,348,554 (30%)	\$39,381,214 (31%)
Total for question 5	\$21,134,241 (2%)	\$125,210,233 (15%)

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Figure 5: Phase I Coding of IACC Subcategories for Question 4 (Treatment) and Question 5 (Services), with levels of implementation

Level	Subquestion
1. Basic Science	Model Systems (4.S.B); Workshop on Subtypes (4.S.E); Health and Mortality (5.S.D)
2a) Pilot Tools	RCT for co-occurring conditions (4.S.A); Efficacy of common interventions (4.S.C); RCT of EI (4.S.D); RCTs derived from biological signatures (4.S.F); Interventions for non-verbal individuals (4.S.G); Prevention of secondary conditions (4.S.H.); RCT on medications for core symptoms (4.L.A); Interventions for siblings (4.L.B); Medications for co-occurring conditions (4.L.C);
2b)	None
3a) Assess Delivery	Self-Directed services (5.S.B); Health and self-determination (5.L.D); Dental Services (5.L.E)
3b) Improve Delivery	Community-Based Interventions (4.L.D); Treatments in diverse settings (5.L.A); Effectiveness of community services (5.L.B)
4a) Assess Access	Impact of access on families (5.S.A);
4b) Improve Access	None
5a) Assess Capacity	Evaluate training (5.L.C)
5b) Increase Capacity	Model state coordination (5.S.C)

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Figure 6: Level of implementation of subcategories of projects focused on Treatment (Q. 4) and Services (Q. 5) from 2008 to 2013, for NIH relative to other agencies

<u>Level of Implementation</u>	<u>Funds allocated (% of total for Q. 4)</u>	
	NIH	All other agencies
I. PRE-IMPLEMENTATION		
1. Basic Science	\$77,739,271 (36%)	\$84,641,185 (29%)
2. Preparing for implementation		
a) Pilot tools	\$119,960,461 (55%)	\$95,369,067 (32%)
b) Specialized delivery	\$0	\$0
II. IMPLEMENTATION		
3. Delivering services in community settings		
a). Assess delivery	\$1,491,688 (>1%)	\$1,111,055 (>1%)
b) Improve delivery	\$14,308,019 (6%)	\$59,006,011 (20%)
4. Closing gaps for underserved populations		
a) Assess access	\$3,741,946 (2%)	\$2,995,444 (1%)
b). Improve access	\$0	\$0
5. Increasing system capacity		
a) Assess capacity	\$1,218,104 (>1%)	\$48,087,658 (16%)
b) Build capacity	\$0	\$5,465,315 (2%)
	\$218,199,489	\$296,675,725

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Figure 7: Phase 2 coding of individual projects for Question 4 (Treatment) and 5 (Services)

