Defining a Research Domain in an Emerging Technology:

Vaccine Research in the State of Georgia

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Introduction

In economies where knowledge is paying an expanding part in competitive performance, learning to measure knowledge has become of increasing importance. How economies obtain and use knowledge is studied in great detail on many levels, including globally, nationally, and regionally. There has been particular interest in the ability to measure emerging technologies. However, this focus on gauging the presence of emerging technologies in knowledge-based economies has proven difficult, especially at the regional level, where still many measures of knowledge are aggregate. However, due to global competition, electronically available data, and an increased attention toward the parts regions play in emerging technologies, finding methods to measure a region's indicators has become of more significance (Youtie 2007). Within these emerging technologies, there are often times a combination of mature and emerging components, which can make it even more difficult to distinguish and define these emerging domains.

Biotechnology is a broad example of an emerging technology. Like many other technologies, its presence is measured generally by knowledge outputs such as publications and patents (as well as spin-off companies). Other measures important in assessing this emerging technology's regional characteristics include research collaborations and networking, and research and development (R&D) resources. A region's resources may also be crucial for its success and growth within a specific area. For and example, previous studies indicate that biotechnology firms are more likely to evolve around universities where star scientists are located (Zucker, 1998). Other studies demonstrate that more technological advances may exist in geographical areas with a high concentration of public and private research facilities (Mangematin 2006, Zucker 2005).

Yet often these emerging technologies exist within a broader more mature field of science and technology. This is the case with biotechnology, some aspects of which overlap with established fields of science even as its developments are changing the nature of these established fields. One example is the overlap between the mature industries of pharmaceuticals relative to the new gene-based therapies. It can be a challenge to try to distinguish these emerging and mature areas.

The aim of this article is to describe an approach for measuring emerging technologies in the context of mature industries. In particular, this article focuses on vaccine-related research. Although vaccines comprise an established industry, new developments in biotechnology have led to emerging area in vaccine R&D, including therapeutic vaccines; subunit and DNA-based vaccines; advances in vaccine delivery; and new methodologies for vaccine design, manufacturing, and testing. This article will demonstrate the challenge involved in measuring these areas not only because they are emerging technologies but also because they are embedded in a mature vaccine industry. Defining this field is also challenging due to the fact that it spans multiple disciplines, including biotechnology, public health, and epidemiology. To gain an understanding of the field as it is related to biomedical research, we focused our study parameters to concentrate on these aspects of vaccine technology.

We will focus on the state of Georgia, which is not a traditional region for biotechnology developments, including traditional vaccine research (Cortwright 2002, Shapira 2006, Youtie 2007). Although still well below the national average, Georgia does possess some useful resources and has been able to obtain some significant funding. The governor of Georgia, Sonny Perdue, has recommended $10 million in state funding be used to recruit top researchers in vaccine and immunotherapy development. The state is home to the Centers for Disease Control and Prevention (CDC), which have an established vaccine-research record both traditionally and currently. Georgia possesses four medical schools at Emory University, the Medical College of Georgia, Morehouse University, and Mercer University. Emory University has recently started a Vaccine Center, which as received over $200 million in external research funding (Korschun 2007). Georgia also contains several companies performing vaccine R&D, including GeoVax, BioSante Pharmaceuticals, and Merial Ltd.

Due to the state of vaccine research globally and due to these recent establishments of affiliations and funding, organizations in the state, such as the Georgia Research Alliance, has begun new initiatives in hopes of improving its position by targeting this emerging industry. To support such initiatives, however, it is helpful to have information on the region's scientific and technical capabilities, its established and rising scientists, and its areas of strengths and weaknesses within the field (Barker 2007).

To delineate the emerging areas of vaccine and the mature ones, we will employ a field scoping method based on expert knowledge and exploratory analysis. Taking a comprehensive outlook on the field can be useful in determining a search strategy or to obtain a clear understanding of keywords to concentrate on. For our knowledge measurements, we will use a multi-dimensional knowledge output approach, employing a combination of measures such as research article publications, citations, patents, keyword analysis, etc. It will be noted that use of multiple databases necessarily introduced some inconsistencies in the ability to delineate emerging technologies because of differences in the database interface. We will vary our perspective from simple counts to more complex network maps, and will look at Georgia's top scientists (and how they are integrated into the overall vaccine research network), top affiliations, its commercialization capacity, and its specializations and gaps in specific vaccine research areas.

A multi-disciplinary team was created for this study to gather and analyze information. The lead author is a biomedical engineer with expertise in vaccine research, which was important for scoping the field, and co-authors are social scientists with expertise in publication analysis. Having a combination of perspectives embodied this study with new and difference outlooks, and contributed to the overall success of this study.

A Brief History of Vaccine Research

Until the mid 1990s, the vaccine R&D coalesced around an established industry that used preventative models underpinned by live or inactivated pathogens. Business activity concentrated on five large pharmaceutical companies, Chiron (Emeryville, UK), GlaxoSmithKline (Brentford, NJ), Merck (WhiteHouse Station, NJ), Wyeth (Madison, NJ), and Sanofi-Pasteur (Lyon, France) (Roth 2007). However, due to breakthroughs in genomics, molecular biology, and immunology, a new surge of vaccine development has been observed. Not only are the five major vaccine companies concentrating on new technologies but other larger companies, smaller start-ups, and academic institutes are becoming active in the field.

Underlying these developments is a shift in the vaccine research paradigm towards the design and employment of new kinds of vaccines. Traditionally, vaccines were either live (or attenuated) pathogens (disease-producing micro-organisms) or inactivated pathogens. These kinds of vaccines involved delivery of the entire, or most of, the pathogenic organism. This type of vaccine presents potential risk by introducing components of a pathogen to a patient, and these vaccines are difficult to manufacture.

New kinds of vaccines, namely subunit and DNA-based vaccines, have since emerged and typically work by focusing the immune response to a specific part of the pathogenic organism. Subunit vaccines are made up of small parts of the pathogenic organism, such as a specific antigen or a specific capsid component. DNA-based (or gene) vaccines are vaccines that carry a specific sequence of DNA that can either translate into a component of the pathogenic organism, or a component involved in or assisting the immune system. These kinds of vaccines can also work by helping to guide the immune system to target cells, or by helping the immune system to become more efficient in responding to specific targets (such as a pathogen or a cancer cell).

Besides the types of vaccines, the industry is also focusing on a new therapeutic approach to the field. Traditionally, vaccines were strictly preventative. However, therapeutic vaccines are increasingly emerging for diseases such as cancer, AIDS, and Alzheimer's disease. For example, therapeutic or toxin genes have been utilized as cancer vaccines, as well as certain components that attract the immune system to previously ignored tumor cells.

The emerging components of the vaccine field are also concentrating of improving vaccine design and manufacturing, as well as enhancing delivery methods for more efficient delivery to target cells.

Although patterns in emerging vaccine research areas can be observed, it is still difficult to understand and measure the field due to its embeddedness in the traditional technology. One of the primary goals for this study is to define the scope of the field to better delineate these areas, though they may still be necessarily integrated together.

Methodology

In order to gain a comprehensive outlook on the vaccine research field, we employed a multi-faceted approach to measuring knowledge outputs. We utilized a combination of the following in our study: field scoping, bibliometrics, list development, keyword analysis, and network exploration.

Field Scoping

First, we performed a field scoping whereby we developed terms associated with various aspects of the vaccine field. This can be useful in determining a search strategy or to obtain a clear understanding of keywords to concentrate on. Table 1 summarizes key concepts that can be distinguished in vaccine research.

Table 1
Pilot Field Scope: Key Concepts in Vaccine Research

Vaccine Types	Vaccine Development	Vaccine Delivery	Therapeutic Vaccines
Live	Design	Intravenous	Cancer
Inactivated	Propagation	Intramuscular	Alzheimer’s Disease
Subunit	Purification	Intra-Dermal	Addictions
DNA-based	Storage	Intra-Nasal	
		Oral	

Source: Author’s analysis of the general scope of the vaccine research field using various information databases, including PubMed.

Bibliometrics

Next, we chose specific data sources relevant for extraction of biomedical research articles. Bibliometric searching is an important tool for gaining relevant knowledge output measurements in a specific field. The central component of our analysis is an examination of vaccine-related publications along with patents and journal editors, to ascertain Georgia’s research and development position relative to the US in emerging vaccine areas.

Several data sources were used in this study. The primary data source used for analyzing the quantity of journal article publications was PubMed. PubMed is a free biomedical literature search and retrieval system provided by the National Center for Biotechnology Information (NCBI). Articles can be accessed from this database through text-based and bibliographic searches. PubMed provides articles from the National Library of Medicine’s (NLM) database, MEDLINE, which encompasses a large set of life sciences fields and more than 5,000 biomedical journals from around the world. PubMed also includes journals outside of MEDLINE that are approved by the NLM. One weakness of PubMed is its exclusion of citation information, which, besides publications number, is an important indicator of researcher influence and ranking. To obtain this type of citation information, we utilized the Thomson Scientific’s Web of Science (WOS), specifically its Science Citation Index, which provides detailed analysis and reports on article citations by authors and their affiliations. Finally, we employed the website of the United States Patent & Trademark Office (USTPO) to search for either granted patents or patent applications in the state of Georgia. Together, we will use these three data sources to complete a comprehensive evaluation of the vaccine research industry in the US and Georgia.

In order to create a knowledge base of journal article publications relating to vaccines and immunotherapies, PubMed was used to extract all relevant articles. The first step in this approach was to determine a search term strategy, which could be employed in PubMed to locate and retrieve desired articles in our field of choice. We chose to use a key search term that covered the entire vaccine research field as conceptualized above (Table 1), which can then be further focused by various types of exclusions. We chose to start with the term "vaccine," specifically with the wild card search term of "vaccin*" (which will include any word that begins with the letters "vaccin") (Table 2). This search term was chosen based on a review of Medical Subject Heading (MeSH) terms, a tool in PubMed that assigns specific standardized keywords to journal articles, whereby it was confirmed that "vaccine" was the broadest category available that encompassed all sub-fields needed for our purposes.

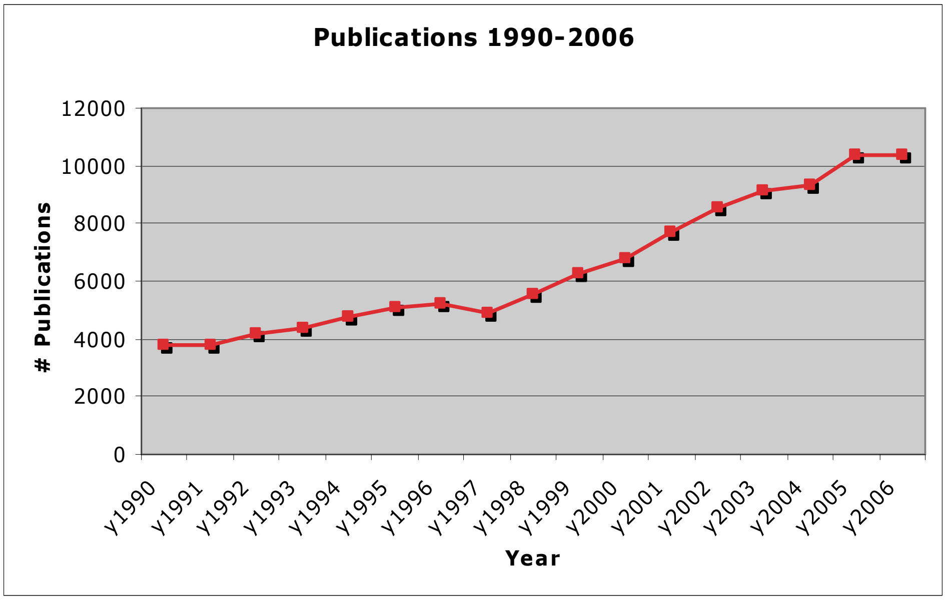
Table 2
Search Term Strategy

	Search Terms	# articles retreived	# articles eliminated
	Vaccin*	183308	
	Vaccin* (Limits: published 01/01/1998 – 07/30/2007)	79311	
#1	Vaccin* (Limits: published 01/01/1998 - /7/30/2007, Clinical Trial, Meta-Analysis, Randomized Controlled Trial, Review, Case Reports, Classical Article, Clinical Trial, Phase I, Clinical Trial, Phase II, Clinical Trial, Phase III, Clinical Trial, Phase IV, Comparative Study, Controlled Clinical Trial, Evaluation Studies, Government Publications, In Vitro, Journal Article, Multicenter Study, Research Support, N I H, Extramural, Research Support, N I H, Intramural, Research Support, Non U S Gov't, Research Support\, U S Gov't\, Non P H S, Research Support, U S Gov't, P H S, Technical Report, Validation Studies)	73077	6234
#2	epidemiol* OR transmiss* OR cost OR econom* OR trend* OR history OR parent* OR education OR "vaccination coverage" OR supply OR policy OR travel* OR mother* OR demograph* OR legal* OR guideline*	330690	
	#1 NOT #2	45511	27566
#3	live vaccine* OR attenuated vaccine* OR inactivated vaccine*	11208	
	#1 NOT (#2 OR #3)	42628	36683

Source: Author's analyis of PubMed publication database relative to vaccine-related publications

In order to gain a relevant insight into the current trends and current key investigators in vaccine research, we conducted a small analysis of publications by year (1990 – 2006) and saw a sharp increase in publication number occur between 1997 and 1998 (Figure 1). To this end, we limited the search for articles to those that were published within the last ten years, specifically between 01/01/1998 and 07/30/1997 (Table 2). This limitation would indicate information that is relevant for a contemporary outlook on the field as well as for identifying scholars who are currently active in vaccine research.

Figure 1:
Publications Related to Vaccines in PubMed



Source: Author's analysis of PubMed publication database relative to vaccine-related publications

This limited set of articles cover a variety of sub-fields in vaccine research, including public health and epidemiology. In order to focus our search more specifically for biomedical research articles, we performed a further limitation, which specified the publication type included (Table 2). PubMed categorizes articles under a number of publication types, including clinical trials, journal articles, reviews, and letters. To extract information specifically from life sciences research articles, we limited publication types to the following: Clinical Trial, Meta-Analysis, Randomized Controlled Trial, Review, Case Reports, Classical Article, Clinical Trial, Phase I, Clinical Trial, Phase II, Clinical Trial, Phase III, Clinical Trial, Phase IV, Comparative Study, Controlled Clinical Trial, Evaluation Studies, Government Publications, In Vitro, Journal Article, Multicenter Study, Research Support, N I H, Extramural, Research Support, N I

H, Intramural, Research Support, Non U S Gov't, Research Support\, U S Gov't\, Non P H S, Research Support, U S Gov't, P H S, Technical Report, and Validation Studies.

These limitations have greatly focused our search to more relevant vaccine research articles. However, a large number still remain in fields outside biomedical research. Therefore, we began to search for a combination of exclusion terms to narrow the focus even further. Each potential term was used in combination with the Boolean operator "NOT". For each term, the list of publications resulting from the exclusion was compared to the original list resulting from "vaccin*" (with all previously discussed limitations). The two lists were used determine if any pertinent articles were removed, or to determine if more exclusions needed to be added. The exclusion terms finally employed for our search strategy were epidemiol*, transmiss*, cost, ecconom*, trend, history, parent*, education, "vaccination coverage", supply, policy, travel*, mother*, demograph*, legal*, and guideline* (Table 2).

This combination of limitations and exclusions has produced a list of articles that adequately covers the field of vaccines as it pertains to biomedical research. A review of these publications indicated a current trend in research previously discussed involving specific kinds of vaccines. There are several primary categories of vaccines, live (or attenuated), inactivated, subunit, and DNA-based. A vast majority of the emerging research focuses on subunit and DNA-based vaccines. By focusing our search strategy on new kinds of vaccines, we were able to make a separation between the emerging and the traditional components of vaccine development. We chose to eliminate articles focusing on live or inactivated vaccine research (Table 2). This elimination was performed by including three more exclusion terms: “live vaccin*,” “attenuated vaccin*,” and “inactivated vaccin*.

This final list of life sciences vaccine research publications, 42,628 total (Table 2), were transferred to a text-mining software program, VantagePoint, and was subsequently analyzed for patterns and trends, and for list development.

The number of research journal articles an author has is an important indicator of his/her productivity in their field. Another important indicator is the citation number, or the number of times their published article has been cited in another article. This number reveals not only the quantity of published work by an investigator but also the quality or importance, specifically the importance given by another researcher. Because PubMed provides no citation data, we used the WOS to locate this information. We used a mixed search method by looking up individual authors and searched for their article citation statistics using the author’s name and the Province/State limitation of “GA.” We limited our citation search to the years 1998–2007 to coincide with the PubMed searches.

In addition to publication and citation numbers, another important indicator of a researcher’s potential commercial impact is their number of patents. In order to find a comprehensive list of vaccine-related patent holders from the state of Georgia, we employed the website of the USPTO (http://www.uspto.gov/patft/index.html). This site allows the user to search for both granted patents and patents that have been applied for. We used the USPTO’s simple online interface, which only allows limited searching capabilities, employing the simple search string “vaccine” as a description and “GA” as the inventor’s state, with the time frame of 1998 to the present. As with the publication information, all patent information was transferred to the text-mining software for further analysis.

To validate our search strategy, we utilized a list of individual Georgia scientists provided to us by the Georgia Research Alliance. We performed our search strategies for all parameters including publications, citations, granted patents and patent applications. Although a majority of these researchers were included within one of these searches, some were focused on basic scientific areas rather than specifically on vaccines.

Findings

With our newly created dataset of biomedical vaccine research information, we created lists indicating Georgia's top resources, including scientists and affiliations. These lists included the most published and cited authors in the field for the US and Georgia, as well as top affiliations according to publication and citation counts. In addition, we generated lists of the Georgia scientists with the most granted patents and the most patent applications, as well as Georgia's top affiliations according to granted patents. Using these lists, we observed that several researchers from Georgia are ranked among the top in the US and that Emory University and the Centers for Disease Control & Prevention (CDC) are in the top ten affiliations in the US.

It was important to compare Georgia and the US in their share of vaccine research to all life sciences research in part because Georgia is not well known for having strengths in the broad biotechnology industry. Our bibliometric analysis showed us that while Georgia produced 1% of all life sciences publication in the US (from 1998 until the present), they produced 3% of all biomedical vaccine publications in the US during the same time period.

We supplemented our bibliometric publication and patent data, with editorial board member information from top journals publishing vaccine research (a list of the top vaccine journals was generated from our publication dataset). This information was helpful but limited due to interfaces that did not allow us to focus on specific areas of research. Also, these journals cover a multitude of subjects in addition to vaccines and immunotherapies, but this analysis gives an adequate indicator as to the standing of researchers who serve as "gatekeepers" within their fields. Our list reveals that several Georgia scientists serve on editorial boards, with some participating on several different ones. Still, some of these scientists do not largely work within the pre-defined scope of the emerging vaccine field, so it is difficult to attribute a substantial "gatekeeping" role to them with respect to this emerging field.

To obtain a scope of the vaccine research specializations in the US and Georgia, including areas of emphases and gaps, we conducted a keyword analysis using the previously discussed MeSH terms used by PubMed. The aim was to use these terms in a way that would distinguish Georgia's strengths and weaknesses compared to the US. We initially tried statistical methods such as factor analysis but the results did not yield any validly interpretable differences. Thus we determined that manually grouping the keywords into broad categories would give the most useful knowledge, and would facilitate an understanding of how vaccine research is conducted nationally and regionally (Table 3). This table presents several broad categories of keywords which are defined as follows: 1) Underlying Science (which covers terms dealing with the fundamental science behind vaccine research); 2) Disease Areas (e.g. AIDS, cancer); 3) Types of Vaccines (e.g. DNA-based vs. subunit); and 4) Vaccine Design, Manufacturing, and Testing.

Table 3
Grouped MeSH Terms

Underlying Science	**# Hits in USA**	**% USA**	**# Hits in GA**	**% GA**	**%GA/%USA**
Immunology	10650	70	185	40	0.58
Virology	4076	27	161	35	1.32
Bacteria Science	2219	15	65	14	0.98
Protozoa Science	466	3	25	5	1.79
Disease Areas					
AIDS	1647	11	63	14	1.27
Cancer	3364	22	43	9	0.43
Pneumonia	872	6	25	5	0.95
Influenza	578	4	26	6	1.50
Animal Diseases	1542	10	99	22	2.14
Bioterrorism-Related	490	3	22	5	1.50
Types of Vaccines					
DNA Vaccines	2478	16	48	11	0.65
Gene Therapy	*1079*	*7*	*22*	*5*	*0.68*
Subunit Vaccines	2739	18	56	12	0.68
Vaccine Design, Manufacturing, and Testing					
Vaccine Design	1333	9	67	15	1.67
Vaccine Manufacturing	593	4	24	5	1.35
Vaccine Testing (Preclinical)	3717	24	226	49	2.03
Vaccine Testing (Clinical)	2622	17	88	19	1.12

Source: Analysis of author's vaccine-related dataset of PubMed publications, 01/01/1998 – 07/30/2007, MeSH terms grouped according to author's discretion

Within the Underlying Science Group, we can observe that Georgia performs strongly in the categories of Virology and Protozoa Science, and performs at about an equal rate to the US in Bacteria Science. Georgia, however, is not as specialized in the area of Immunology as compared to the entire US.

When focusing on the types of disease that are primarily researched in Georgia and the US, we included categories of disease that occurred the most frequently within our MeSH term analysis, including AIDS, cancer, pneumonia, influenza, animal diseases, and bioterrorism-related diseases (which include diseases most associated with bioterrorism, smallpox and anthrax). In our investigation, we can see that, as compared to the US, Georgia focuses highly on AIDS, influenza, animal diseases, and bioterrorism-related diseases. The state's strong emphasis on AIDS may come in part to the focus at Emory University, including the Emory Center for AIDS Research, which was recently awarded $8.5 million by the NIH. The Emory Vaccine Center also has a major focus on HIV/AIDS research. The CDC has a National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, which may also assist the state with its strong AIDS record.

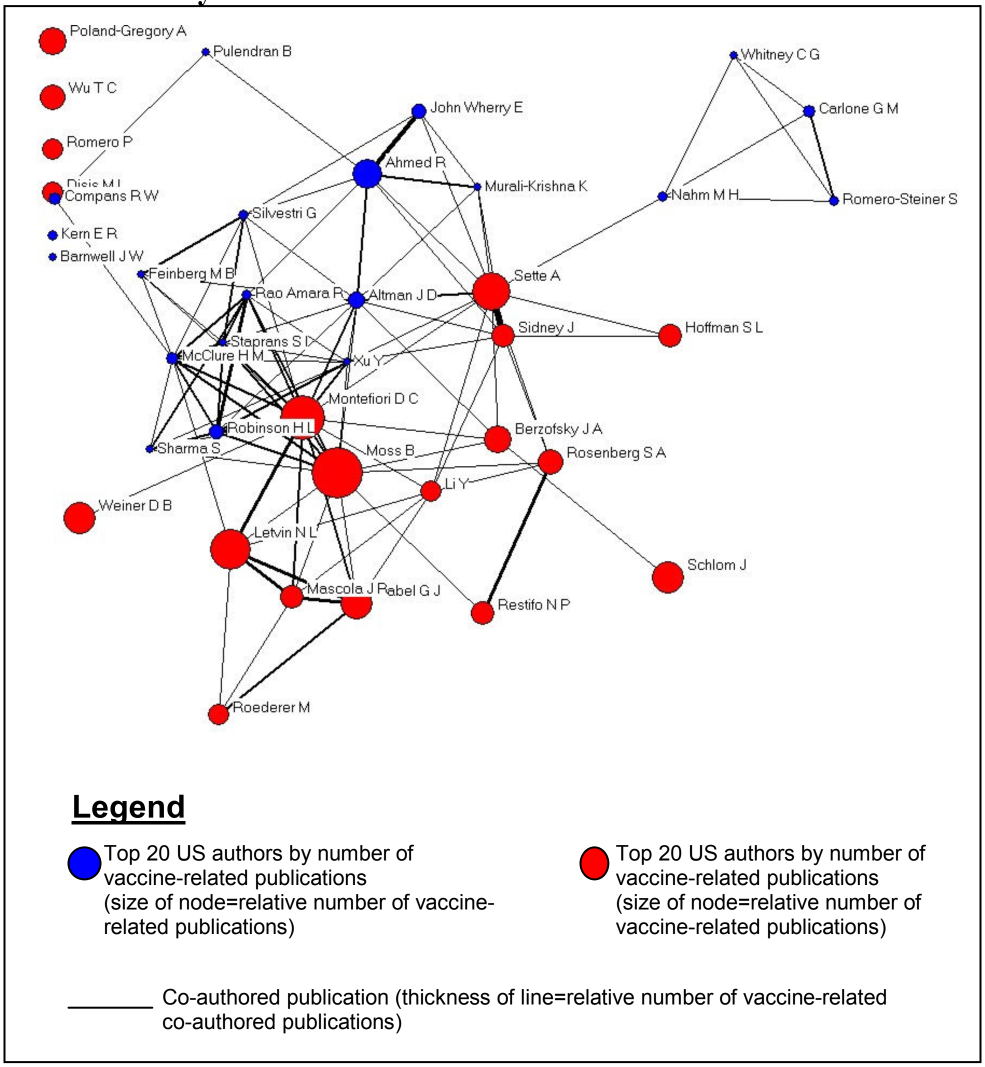
Georgia performs at about the same rate as the US in Pneumonia research, which is also likely due to the CDC's participation. As compared to the US, Georgia appears to not be as specialized in cancer research. This may be due to the lack of a major cancer center within the state (such as found at Sloan-Kettering).

The next grouping we concentrated on was Vaccine Types. As discussed previously, we chose to focus more on newer types of vaccines, namely subunit and DNA-based ones, in order to gain the most current outlook on the field. To note within this group is that the category Gene Therapy also falls under the DNA-based Vaccines group, but here it is also shown alone due to its high prevalence within the vaccine field. In all types of vaccines listed here, we can discern that Georgia does not appear to be as specialized in these areas as the rest of the country. These numbers most likely indicate that vaccine types are not as focused on as a research specialization *per se* in Georgia, but may function more as tools used in other research areas.

Finally, we analyzed the terms relating to how vaccines are designed, manufactured, and tested both pre-clinically and in the clinic. Here, Vaccine Design covers terms related to drug design on molecular, biochemical, protein, or biomaterial levels. Vaccine Manufacturing encompasses terms related to how, once designed, vaccines are produced and propagated, as well as, cleaned and stored. In both of these categories, Georgia appears strong when compared to the nation. In the Vaccine Testing (Preclinical) category, Georgia is also more specialized. When looking at clinical trials, Georgia appears to be as similarly specialized as the US in its participation in this form of vaccine testing.

Another measure of position for an emerging technology such as vaccine research is the degree to which scholars and institutions are networked within the broader research community. We have examined this based on the number of co-authored publications. A region's position can be ascertained based on the extent to which its top investigators co-author with other leading scholars within the field, determining if a region is sufficiently integrated. Some scholars from Emory University were very integrated within the network while others (many of which were at the CDC) were not as integrated. This type of analysis suggested further opportunities for the state to become more integrated into this important scholar network.

Figure 6
Network Analysis of Co-Authored Publications



Source: Analysis of author’s vaccine-related dataset derived from PubMed publication database, 01/01/1998 – 07/30/2007.

Conclusions

We have reported here a multidimensional approach to defining an emerging field, specifically vaccine research, within an established field and applied this to the measurement of the positioning of a regional knowledge-based capability. We have employed an analysis observing the field from various viewpoints, including research outputs (publications, citations), intellectual property, collaborations, editorial participation, and emphases and gaps within specific areas. We used Georgia as our model although other regions could be used as contexts as well.

The field of vaccine research was noted to include both an emerging new aspect and a traditional component, and it covers a wide variety of disciplines. Therefore, we performed a general field scoping of the vaccine research area to obtain a better understanding of its outlook. We then formulated a bibliometric search strategy for the retrieval of vaccine research publications, citations, and patents, narrowing the focus to life science research using limitations and exclusions. We also focused our search to exclude references referring to mature components of the field, namely live and inactivated vaccine types. All references were analyzed with text-mining tools to identify important resources for the state of Georgia. We found that Georgia does have a presence within the field with certain areas of emphasis, and it also has areas of opportunity.

The primarily disaggregated measures here facilitated a more finely focused prespective on the emerging vaccine area in this particular region, which is difficult to achieve when using aggregated measures. We also utilized a multi-disciplinary team of analysts, including some with subject expertise in vaccine research and others with social science analysis experience. This was crucial for a thorough and accurate exploration of the field. Although there are limitations to this approach, particularly in its need for embedded knowledge with experts in the emerging field taking a large role, this approach can be useful in fostering an enhanced understanding of the region relative to the emerging technology in question.

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