The Silver Book®: Parkinson’s Disease

Parkinson’s disease is a progressive neurological disorder that leads to debilitating symptoms, comorbidities, expensive medical care, and caregiving needs. Existing therapies help manage symptoms and exciting research advances hold promise for even better management and potential cures.

Prevalence & Incidence

~1 MILLION AMERICANS have PARKINSON’S DISEASE (Marras et al 2018 AND Hamilton & Yang et al. 2019)

MEN ARE 1.37x MORE LIKELY to have Parkinson’s disease than women (Hamilton & Yang et al. 2019)

In the U.S., Parkinson’s disease is the 2ND MOST COMMON NEURODEGENERATIVE DISORDER (NINDS 2018)

EVERY 9 MINUTES, someone in the U.S. is DIAGNOSED with Parkinson’s disease — ~60,000 NEW cases each year (Parkinson’s Foundation)

The Silver Book®: Chronic Disease and Medical Innovation in an Aging Nation is an almanac of thousands of facts, statistics, graphs, and data from hundreds of agencies, organizations, and experts. These statistics spotlight the mounting burden of chronic diseases that disproportionately impact older Americans, and the promise of innovation in mitigating that burden.

Launched in 2006, The Silver Book® has become a trusted resource for health policy practitioners and thought leaders and has featured volumes and factsheets on valve disease, osteoporosis, thrombosis & atrial fibrillation, heart disease, persistent pain, cancer, healthcare-associated infections, infectious diseases & prevention through vaccination, vision loss & diabetic retinopathy, diabetes, and neurological diseases. All data is available online at www.silverbook.org, where users can access more than 3,000 facts, statistics, graphs, and data from more than 800 references. All data is cited and when possible, linked to the original source online.

www.silverbook.org/parkinsons
SilverBook@agingresearch.org
Human Burden

>23 THOUSAND

PREMATURE DEATHS

associated with Parkinson’s disease

in 2017 (Hamilton & Yang et al. 2019)

MORTALITY

>3x GREATER

for PEOPLE WITH PARKINSON’S than for those without the disease (Hamilton & Yang et al. 2019)

E X P E R I E N C E of Americans with Parkinson’s over 1 YEAR

(Obrien et al. 2009)

54%

Are chronic and managed on an out-patient basis

11%

Spend the year in an institution

23%

Are chronic, non-institutionalized, and experience an acute event

12%

Die

DEMENTIA is NEARLY INEVITABLE for people with Parkinson’s disease — affecting MORE THAN 80% of people followed for >20 YEARS after disease onset (Rundo et al. 2016)

Depression may affect:

UP TO 50% of people with Parkinson’s disease

— YET 40% DO NOT receive treatment (Tandberg et al 1996 AND Ravina et al. 2007)

>1/2 of people with Parkinson’s eventually develop symptoms of PARKINSON’S DISEASE PSYCHOSIS (Forsaa et al. 2010)

~60% of people with Parkinson’s disease report at least one fall and recurrent fallers report 4.7 to 67.6 falls per year (Allen et al. 2013)

The risk of suffering a fracture is 2x HIGHER in people with Parkinson’s disease, and the risk of a hip fracture is >3x HIGHER (Melton et al. 2006)

Percentage of People with Parkinson’s who Experience Various Symptoms (Hamilton & Yang et al. 2019)

<table>
<thead>
<tr>
<th>symptom</th>
<th>percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slowed movement</td>
<td>91%</td>
</tr>
<tr>
<td>Tremors</td>
<td>82%</td>
</tr>
<tr>
<td>Poor balance and coordination</td>
<td>89%</td>
</tr>
<tr>
<td>Trouble speaking</td>
<td>70%</td>
</tr>
<tr>
<td>Trouble writing</td>
<td>86%</td>
</tr>
<tr>
<td>Urinary issues</td>
<td>78%</td>
</tr>
<tr>
<td>GI issues</td>
<td>78%</td>
</tr>
<tr>
<td>Sleep issues</td>
<td>86%</td>
</tr>
<tr>
<td>Fatigue and loss of energy</td>
<td>93%</td>
</tr>
<tr>
<td>Difficulty concentrating</td>
<td>78%</td>
</tr>
<tr>
<td>Difficulty with memorizing or recalling information</td>
<td>79%</td>
</tr>
<tr>
<td>Difficulty understanding complex tasks</td>
<td>63%</td>
</tr>
<tr>
<td>Difficulty swallowing</td>
<td>60%</td>
</tr>
<tr>
<td>Vision problems</td>
<td>58%</td>
</tr>
<tr>
<td>Pain</td>
<td>66%</td>
</tr>
</tbody>
</table>

In 2010, Parkinson’s disease was attributed to:

- 26,000 hospice days
- 24,000 home health days
- 31,000 emergency room visits
- 1.26 million physician office visits
- 1.9 million hospital inpatient days (Kowal et al. 2013)

Nearly 1 in 4 Medicare beneficiaries with Parkinson’s disease LIVED IN A LONG-TERM CARE FACILITY in 2002 (Safarpour 2015)
As part of its initiative to better understand the economic burden of Parkinson's disease, the Michael J. Fox Foundation for Parkinson's Research commissioned The Lewin Group to estimate the economic impact of Parkinson's disease in the U.S., based on 2017 data and completion of a primary survey deployed in the wider Parkinson's disease and caregiver community. The study provides the most comprehensive assessment of the economic burden to date, nearly doubling previous estimates, and for the first time, includes the various ways Parkinson's affects a person's finances and their ability to participate in the labor market. The Economic Burden of Parkinson's Disease, was published with support from Parkinson's Foundation, American Parkinson Disease Association, and The Parkinson Alliance, along with ACADIA, Adamas, AbbVie, Acorda, and Biogen. (Hamilton & Yang et al. 2019)

The FEDERAL GOVERNMENT spends NEARLY $25 BILLION EACH YEAR caring for people with Parkinson's —

TOTAL ANNUAL COST OF PARKINSON’S DISEASE IN THE U.S. = $51.9 BILLION

$25.4 billion in DIRECT MEDICAL COSTS

BY TYPE OF SERVICE

Hospital Inpatient $7.19 BILLION
Outpatient $5.5 BILLION
Physician Office $1.23 BILLION
Durable Medical Equipment $145 MILLION
Prescription Medication $4.14 BILLION
Non-acute Institutional Care $7.14 BILLION

TOTAL $25.4 BILLION

$26.5 billion in INDIRECT MEDICAL COSTS

BY TYPE OF SERVICE

$7.5 BILLION Other non-medical costs
$4.8 BILLION Disability income
$14.2 BILLION Indirect costs

TOTAL $26.5 BILLION

$14.2 BILLION* in INDIRECT and NON-MEDICAL COST by Type of Cost

Average annual direct medical cost per person with Parkinson’s is = $24,439 MORE THAN if they DIDN’T HAVE the disease

Direct medical costs per person with Parkinson’s increase with severity of the disease

Mild $10,256
Moderate $33,515
Severe $60,369

Total $51.9 billion

Indirect costs

Attributable death $2.5 BILLION
Reduced employment $2.7 BILLION
Absenteeism $5 BILLION
Presenteeism $3 BILLION
Social productivity loss $1 BILLION

AVERAGE ANNUAL INDIRECT & NON-MEDICAL COSTS per person with Parkinson’s disease =

$19,242

$25,558 when combined with caregiver burden

The federal government spends nearly $25 billion each year caring for people with Parkinson’s —

~$2 billion on social security
~$23 billion on Medicare costs

~90% of the Parkinson’s disease population are on Medicare
Power of Collaboration

Forward-thinking collaborations that bring together stakeholders across sectors offer tremendous promise for breakthroughs. The Accelerating Medicines PD Knowledge Portal that houses data from more than 3,000 people with Parkinson’s and is working to identify and validate the most promising therapeutic targets; and the Biomarkers Across Neurogenerative Disease Partnership that aims to increase understanding of the similarities and differences of neurogenerative diseases; are both important examples of the power of collaboration.

Value of Innovation

**IF PARKINSON’S DISEASE PROGRESSION WAS:**

<table>
<thead>
<tr>
<th>Slowed by 20%</th>
<th>SAVING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>~$75,891</td>
</tr>
</tbody>
</table>

**PER PERSON WITH PARKINSON’S**

| $37,927 | $15,235 |
| in medical costs & in lost income |

*If Parkinson’s disease progression was stopped, it would save ~$442,429 per person with Parkinson’s.*

(Association of American Medical Colleges 2013)

**In 2018, 46 medicines were in development for Parkinson’s disease**

(America’s Biopharmaceutical Companies 2018)

**Exciting momentum in the understanding of Parkinson’s disease holds tremendous promise for breakthroughs in treatment and improved care.** Treatments like gene therapy and stem cell therapy hold the potential to slow and even stop the disease; next generation therapies aim to treat many of the symptoms of the disease, including non-motor symptoms, and may even improve quality of life (QoL); and the quest for biomarkers is being prioritized by researchers. These and other promising advances are bringing hope to people living with Parkinson’s.

**Deep brain stimulation** can REDUCE MOTOR DISABILITY and in one study, added 1.69 quality-adjusted life years (QALY) more than best medical therapy, an incremental cost-effectiveness ratio of:

$23,404 per QALY

(Jetzsch et al. 2016)

**A GENE THERAPY** that encodes for the three critical enzymes required for dopamine production, was found in early stage clinical trials to produce a 42% improvement in UPDRS OFF scores and improvements in activities of daily living, 3 months after treatment.

(Lopes 2019)

**Spinal cord stimulation** SIGNIFICANTLY IMPROVED gait disturbance & freezing — improving measures

<table>
<thead>
<tr>
<th>Mean step length</th>
<th>Stride velocity</th>
<th>Sit-to-stand</th>
</tr>
</thead>
<tbody>
<tr>
<td>38.8%</td>
<td>42.3%</td>
<td>50.3%</td>
</tr>
</tbody>
</table>

Also significantly reduced freezing-of-gait (FoG) episodes — from 16 pre-surgical FoG episodes to 0 at 6 months post-surgery.

(Samotus et al. 2018)

**A GENE THERAPY** that makes an enzyme allowing better communication between cells in the nervous system, was found in early stage clinical trials to REDUCE THE AMOUNT OF LEVODOPA the subject needed to take — up to 42% less in the highest dose group.

(Christine et al. 2019)

**Early findings from a STEM CELL THERAPY TREATMENT study found improved motor function** in Parkinson’s subjects with mild to moderate disease.

(Schiess et al. 2019)
Paving the Way for Innovative Treatments

Engaging and Incorporating the Patient and Care Partner Perspective

The participation and perspective of people with Parkinson’s disease are critical to developing effective therapies, yet fewer than 10% participate in research. Participation must be encouraged and facilitated through projects like:

- **Clinical Trial Companion and the Trial Participant Pack** – tools that help educate on what it means to participate in a clinical trial and how to get involved
- **Fox Insight** – on-line clinical study where patients share perspectives to help fuel treatment breakthroughs
- **Genetics Initiative** – national study offering free genetic testing and counselling for Parkinson’s-related genes
- **Parkinson’s Outcome Project** – largest ever clinical study of Parkinson’s disease
- **Parkinson’s Progression Markers Initiative** – observational study of cohorts to identify biomarkers of Parkinson’s disease progression
- **PD Information Questionnaire (PDIQ)** – brings patients together to determine what clinical trial outcomes are most important to them

Ensuring Patient Access to Treatments

Parkinson’s disease patients have unique challenges — often dealing with the complexity of the disease; symptoms that can have substantial social implications; comorbidities like depression, anxiety, and other chronic disease; and elaborate treatment regimens that can include physical, occupational, and cognitive therapy. Treatment delays and/or interruptions in care can cause symptoms to return and new side effects to develop. Given the complexity of the disease, once the most appropriate treatment is identified, access to treatment must be broad and uninterrupted. Utilization management tools should not be used to steer patients to lower cost alternatives if not clinically appropriate; and if used, clear and timely processes must be available for the physician to gain a medical exception when clinically appropriate.

Evolving Payment Models for Gene Therapy

Breakthroughs in gene therapy have enormous potential to transform approaches to Parkinson’s disease treatments. Commercial health plans, manufacturers, and the Centers for Medicare and Medicaid Services will need the regulatory ability to adopt creative payment models to enable the community to broadly benefit from the promise of gene therapy while continuing to enable companies to fund innovation. Possible solutions could include:

- Outcomes-based contracts that share risk
- Installment payment contracts that delay the costs of treatment
- Shared savings across the system
- Commonly funded risk pools for insurers

Safeguarding the FDA’s Workforce and Maximizing Use of Regulatory Tools

As the Food and Drug Administration (FDA) undertakes a major reorganization, it is imperative that the agency hire and retain staff with the neurology and psychiatry expertise necessary to review a new generation of Parkinson’s disease treatments; and that it maximizes the use of innovative regulatory tools. Priorities set through recent legislation must continue to be supported including:

- Creation of pilot programs to modernize and streamline hiring
- Prioritization of efforts to better understand disease domains, patient populations, and improved ways of measuring treatment effect
- Increased use of designations such as Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review, and Regenerative Medicine Advanced Therapy


The Alliance for Aging Research is the leading non-profit organization dedicated to accelerating the pace of scientific discoveries and their application in order to vastly improve the universal human experience of aging and health.

© 2019 Alliance for Aging Research

Acknowledgements:

The Alliance extends its thanks to the following experts for reviewing The Silver Book*: Parkinson’s Disease:

- James C. Beck, PhD
  Chief Scientific Officer
  Parkinson’s Foundation

- Jamie Hamilton, PhD
  Senior Associate Director, Research Programs
  The Michael J Fox Foundation for Parkinson’s Research

The Economic Burden section was produced in partnership with:

This volume of The Silver Book* supported by an educational grant from: