**AF-Related Stroke:**

- Stroke is the 3rd leading cause of death\(^1\)
- 196,000 strokes per year\(^1\)
- 60,000 deaths per year\(^2\)
- 10-12% of all deaths\(^1\)
- AF is the second most important risk factor for stroke\(^3\)

**AF** > smoking > diabetes > physical inactivity

- AF is the second most important risk factor for stroke,\(^3\) bigger than smoking, bigger than diabetes, bigger than physical inactivity

1 in 4 strokes due to AF\(^4\)

**AF-related strokes** are the most debilitating strokes\(^5\)

- 1.5x higher cost\(^6\)
- AF-related strokes compared to strokes not due to AF

- 2x the risk of death\(^5,7\)

More disabling and more likely to lead to admission to nursing home\(^4\)

**Policy Landscape:**

- No national stroke strategy, available only in some Italian regions
- No national plan on the prevention of AF-related stroke
- No national AF registry
- No national stroke registry

**A Growing Economic Burden:**

- Total direct healthcare costs of cerebrovascular disease per year: €2.7 billion\(^8\)
- Total indirect costs of cerebrovascular disease per year*: €1.99 million\(^8\)

**Awareness Gap:**

Most people have never heard of AF and up to 50% do not know very much about stroke\(^9\)...even if the risk of developing AF is 1 in 4 at the age of 40.\(^10\)

**AF:** 1.85% of the population\(^11\)

- At least 1/3 of all cases undetected\(^12-14\)

**Detection Gap:**

**Treatment Gap:**

- Patients on OAC therapy: 46-68% depending on the setting\(^11,15,16\)
- Approximately one third of AF patients at risk of stroke (CHA\(_2\)DS\(_2\) - VASc ≥ 2) are not offered OAC therapy\(^16\) yet many of these would be eligible according to current ESC guidelines.\(^17\)

*This infographic is based on national data where possible. Where national data are not available, international data have been used.
## COUNTRY PROFILE: ITALY

### 1: DATA SUMMARY

#### THE NUMBERS

<table>
<thead>
<tr>
<th></th>
<th>Prevalence of AF (%)</th>
<th>Number of people with AF (prevalence)</th>
<th>Number of new cases of AF per year (incidence)</th>
<th>Number of undetected AF cases</th>
<th>Detection gap</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AF</strong></td>
<td>1.85%</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Stroke</strong></td>
<td>196,000</td>
<td>60,000</td>
<td>10-12%</td>
<td>No data available</td>
<td>No data available</td>
</tr>
</tbody>
</table>

|                | 25.8%                | No data available                      | No data available                             | No data available             | No data available |

#### AF Related Stroke

- % strokes due to AF: 25.8%
- Number of new cases of AF-related stroke per year: No data available
- Prevalence of AF-related strokes: No data available

#### Future Projections

<table>
<thead>
<tr>
<th></th>
<th>AF</th>
<th>Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No data available</td>
<td>Growing prevalence, no estimates available</td>
</tr>
</tbody>
</table>

### THE COSTS

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Total direct healthcare costs of cerebrovascular disease per year:</td>
<td>€2.7 billion</td>
</tr>
<tr>
<td>Total indirect costs of cerebrovascular disease per year:</td>
<td>€1.99 billion</td>
</tr>
<tr>
<td>Annual cost of AF-related stroke:</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### THE POLICY LANDSCAPE

| National plan for AF-related stroke:                          | No             |
| National stroke plan:                                         | No, but some regional plans exist |

### CLINICAL GUIDELINES

| National guidelines on AF-related stroke:                     | Yes (AIAC* 2013) |
| Most relevant to cardiologists:                                | ESC 2012, AIAC 2013 |
| Other guidelines:                                             | Local/regional FCSA** guidelines |

### HOW MANY AF PATIENTS ARE TREATED ACCORDING TO GUIDELINES?

- % AF patients currently treated with OAC therapy: 46-68% depending on the setting
- % AF patients at increased risk of stroke (CHA₂DS₂-VASc ≥ 2) currently treated with OAC therapy: 67-73% (depending on risk of bleeding)

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* AIAC: Associazione Italiana Aritmologia e Cardiostimolazione  
** FCSA: Federazione Centri per la Diagnosi della Trombosi et la Sorveglianza delle Terapie Antitrombotiche
COUNTRY PROFILE: ITALY

2: EPIDEMIOLOGY

AF

<table>
<thead>
<tr>
<th>Number of people with AF (prevalence):</th>
<th>No data available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence of AF (%):</td>
<td>1.85%¹¹</td>
</tr>
</tbody>
</table>

The most recent estimate of prevalence in Italy is from the ISAF (Italian Survey of Atrial Fibrillation Management Study) study of 295,906 patients seen by 233 GPs across Italy. Authors found AF in close to 2% of the population, with rates decreasing slightly from North to South.¹¹ Extrapolated to the Italian population, the prevalence of AF is estimated at 1.85%.¹¹ Other previous studies report similar findings, although many of the estimates are regional.²⁰

Undetected AF
No data available

STROKE

<table>
<thead>
<tr>
<th>Total numbers of people living with stroke (prevalence):</th>
<th>913,000¹ – 950,000²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of new cases of stroke per year (incidence):</td>
<td>196,000¹</td>
</tr>
<tr>
<td>Deaths due to stroke every year:</td>
<td>60,000²</td>
</tr>
</tbody>
</table>

Stroke is the 3rd leading cause of death in Italy and represents 10-12% of total deaths.¹ It is also the leading cause of adult disability.¹ There are approximately 196,000 new strokes every year in Italy, of which 157,000 are first-ever strokes.¹ Estimates of the number of stroke survivors range from 913,000¹-950,000². Thirty percent of people who suffer a stroke (approximately 60,000 people) die within one year, and a third suffer severe and permanent disability.²

AF-RELATED STROKE

A number of studies in Italy have shown that AF-related strokes are more severe and lead to greater disability than those not due to AF.⁴ In a prospective hospital-based study, patients without AF were more often able to go home after stroke than those with AF, and AF-related strokes had greater disability and was associated with a two-fold greater probability of unsatisfactory prognosis in multiple regression analysis.⁴

There are no national estimates of the cost of AF-related stroke. Fattore et al. found that AF increased the cost of hospitalisation for strokes as compared to strokes not due to AF, however this difference was not statistically significant.²¹

3: ECONOMIC BURDEN

STROKE

<table>
<thead>
<tr>
<th>Total direct healthcare costs of cerebrovascular disease per year:</th>
<th>€2.7 billion⁸</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total indirect costs of cerebrovascular disease per year:</td>
<td>€1.99 billion⁸</td>
</tr>
<tr>
<td>Annual cost per AF-related stroke:</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Published data on the total direct and indirect costs of stroke are not available for Italy, however, leading international studies have suggested that direct and indirect costs of cerebrovascular disease represent €2.7 and €1.99 billion per year, respectively.⁸

The total cost per stroke survivor for 12 months following stroke has been estimated to be between €20,000²¹ and €30,000 per person²² depending on the study. Costs of rehabilitation account for 35% of total healthcare costs, and most costs occur in the first 3 months following a stroke.²¹

AF-RELATED STROKE

A number of studies in Italy have shown that AF-related strokes are more severe and lead to greater disability than those not due to AF.⁴ In a prospective hospital-based study, patients without AF were more often able to go home after stroke than those with AF, and AF-related strokes had greater disability and was associated with a two-fold greater probability of unsatisfactory prognosis in multiple regression analysis.⁴

There are no national estimates of the cost of AF-related stroke. Fattore et al. found that AF increased the cost of hospitalisation for strokes as compared to strokes not due to AF, however this difference was not statistically significant.²¹
Government policy and strategy

There is no national plan or strategy for AF-related stroke, nor are AF or AF-related stroke visible in other relevant government policies or improvement initiatives. However, a draft bill on “Cardiovascular diseases, prevention and cure of atrial fibrillation and stroke” was presented by an Italian MP on 30th May 2013, but it has not yet been examined by the parliament.

Stroke plans exist only in some Italian regions, but there are no national government-led improvement initiatives relating to stroke.

Advocacy and awareness

Awareness of stroke is very poor – as was found in a survey conducted by A.L.I.Ce. Italia, Censis and the university of Florence, which found that more than 50% of people did not know very much about stroke, or about available treatment.9 Poor provision of information to patients about how best to manage their OAC therapy is also a concern: in a recent observational study (ISPAF), fewer than 20% of patients received information on side effects of OAC therapy and only 24% received information about interactions with other drugs.16

A.L.I.Ce. Italia has led an active awareness campaign on AF in the last years, providing free screening for AF along with blood pressure measurement in over 3000 pharmacies across Italy. (see Case study 6: Pulse checks in pharmacies in Italy)

There is no national AF registry for AF in Italy, nor is there an official national stroke registry, although some initiatives exist.

Cardiologists tend to follow the ESC 2012 guidelines and the AIAC 2013 guidelines18, which follow the main recommendations of the 2012 ESC guidelines but focus mostly on aspects of AF management other than anticoagulation.18

Other guidelines include local or regional guidelines developed by the FCSA19 (Federazione Centri per la Diagnosi della Trombosi et la Sorveglianza delle Terapie Antitrombotiche) as well as the Stroke Prevention and Educational Awareness Diffusion (SPREAD) 2012 guidelines.1

The initial prescription of OAC therapy in Italy is usually made by a cardiologist, internist or other specialist (e.g. neurologist) with GPs ensuring follow-up and management of co-morbidities in patients on OAC therapy.20
The table above shows recently published data on OAC therapy use in Italy. In the ISAF study based on patients recruited by GPs across Italy, only 46% of all patients received OAC therapy, 27.5% received antiplatelet therapy, and 16.5% received no antithrombotic therapy at all. In the same study, 28.4% percent of patients on rhythm control were treated with OAC therapy, as compared to 59.6% with rate control. In the ATA-AF study based in cardiology clinics, 59% of patients with CHADS2 scores other than 0 receive OAC therapy, (7.8% of whom are on both OAC and antiplatelet therapy) and 19% of patients are not receiving any antithrombotic therapy at all. Volterrani et al. found that the percentage of patients at high risk (CHA2DS2-VASc ≥ 2) not receiving OAC therapy was 27% for patients with high bleeding risk, and 33% for those at low bleeding risk.

Evidence also suggests that OAC use is not greatly correlated with stroke risk, indicating that stroke risk stratification systems are not yet fully incorporated into clinical practice. High risk patients are often under-treated and low-risk patients are often over-treated (see next page). For example in the ATA-AF study, 47% of patients with CHA2DS2-VASc risk of 0 were prescribed OAC therapy. Under-treatment is a particular problem in internal/general medicine (MED) settings, possibly reflecting the greater propensity of multi-morbid patients who present to internists, as compared to specialists. Under-treatment also increases with age – for example, age accounted for half of the reasons why OAC therapy was not prescribed in the ATA-AF study.

Antithrombotic treatment by CHA2DS2-VASc score is illustrated below from the ATA-AF study.
**7: ADHERENCE TO GUIDELINES (CONT’D)**

**Percentage of use of OAC therapy in non-valvular AF patients, by CHA\textsubscript{2}DS\textsubscript{2}-VASc score.**

Adapted from Gussoni et al. 2013\textsuperscript{15}

**Quality of OAC care:**

Low persistence with OAC therapy is also an important concern. Mazzaglia et al. (2010) found that persistence rates fell from 42.5% the first year to 24.3% the second year.\textsuperscript{24} Another study in primary care found that 84% of patients were prescribed OAC therapy, however 64.8% discontinued therapy in favour of antiplatelet therapy within two years.\textsuperscript{20} Suboptimal treatment in terms of the time spent within the TTR for INR readings is also an issue, with patients only spending approximately 50% of their time within TTR.\textsuperscript{26}

Italy has a wide network of anticoagulation clinics (‘TAO centers’). These work in partnership with the patient association Feder AIPA and with the national regulatory agency AIFA. These centres play an important role in providing GP education, patient education, and overall management of patients. Because of capacity, only 30% of AF patients are treated in TAO centers. Discussions are currently ongoing between primary care physicians and TAO centres to try to unify standards of care across all settings of care.
8: REFERENCES


