

# INTRODUCING THE

# *“COAGU-PROJECT”*

## HEALTHCARE COST

## BURDENING MODULE

MARCELLO RUSPI, MD

C. ENRICO VENTURI, ENG

**ATTENZIONE.** IP DOTT. MARCELLO RUSPI, 2014. SI VIETA  
ESPRESSAMENTE LA COPIA E LA DIFFUSIONE DI QUESTO  
DOCUMENTO SENZA PERMESSO SPECIFICO. OGNI ABUSO  
VERRA' PERSEGUITO A NORMA DI LEGGE

# KEY DRIVERS

**STROKE**

**EPIDEMIOLOGY**

**ATRIAL FIBRILLATION** (NON VALVULAR)

**VENOUS DEEP THROMBOSIS**

**CARDIAC MECH PROSTHESIS**

**USE CASES**

**MEDICAL THERAPIES**

**LABORATORY TEST**

**PREVENTION**

**PICTURE OF ITALY**

**COAGU-CHEK**

**TELEMEDICINE**

**REFUND**

**BUSINESS**

# STROKE

***IS THE THIRD CAUSE OF DEATH***  
(12% OF ALL THE DEATHS)  
AFTER IMA AND CANCER

IS THE FIRST CAUSE OF DISABILITY

200.000 STROKE IN ITALY / YEAR  
15 MILLION PEOPLE WORDWILDE / YEAR

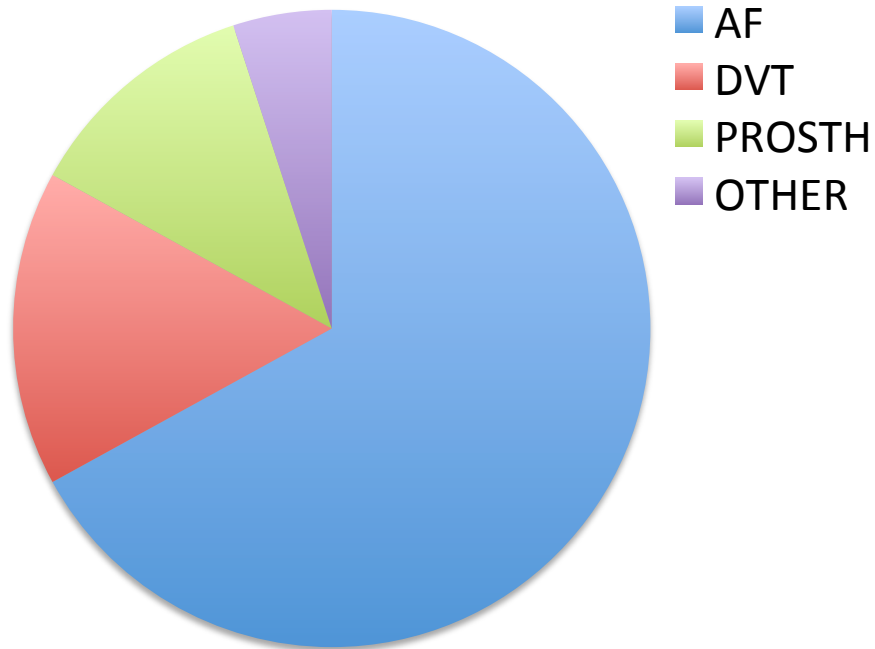
***COMMONLY FOR ATRIAL FIBRILLATION***

PREVALENCE INCREASES WITH THE AGE  
IN A INCRESINGLY AGEING POPULATION  
WHERE >>10% OF OVER-80s HAS AF

# EPIDEMIOLOGY

COAGULATION RELATED DISEASES  STROKE

ELDER PEOPLE IN AOC



# NUMBERS OF STROKE / Y (15 MILL/Y WORLDWIDE)

COUNTRY	STROKES	EMBOLIC STROKES	DEATH	LIVING WITH EFFECTS	GLOBAL COST *
USA	800.000	125.000	130.000	610.000	36,5 USD BILL
UK	110.000	50.000	60.000	900.000	10 BILL
FRANCE	NO RECENT DATA	-	-	-	8 BILL + INS
NEW ZEALAND (pop 4.400.000)	6.000	2.000	3.000	(5 YEARS MONIT. FOLLOW-UP)	450 MILL (2015 700 MILL)
ITALY	200.000	50.000	65.000	930.000	14,5 BILL

\* GLOBAL COST INCLUDES LOST PRODUCTIVITY, DISABILITY, CAREGIVING ETC

25% RECURRENT      87% ISCHEMIC      20% FATAL      36% IN INDIVIDUAL AGED > 80

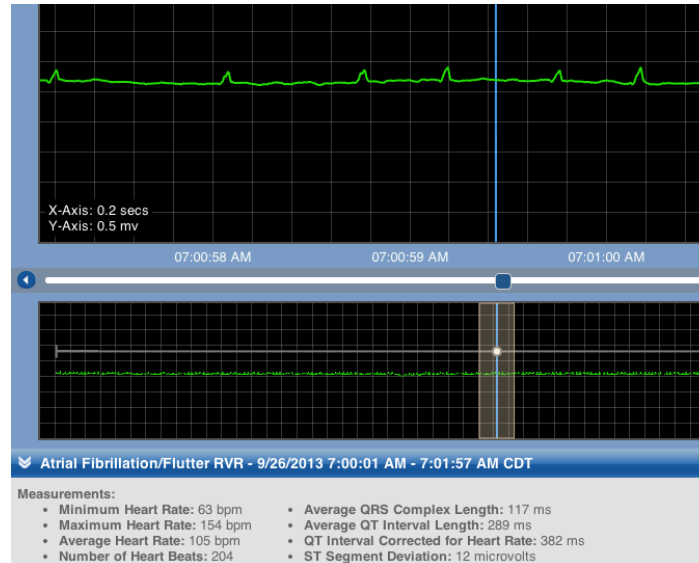
20% OF ALL ACUTE HOSPITAL BEDS AND 25% OF LONG-TERM BEDS

AVERAGE COST FOR IN H ACTIONS/STROKE € 30.000

INCREASING 5-8%/Y

# USE CASES

## NON-VALVULAR ATRIAL FIBRILLATION



2% OF THE POPULATION SUFFERS FROM ARRHYTHMIAS  
MOSTLY (65%) AS AF THAT INCREASES > 5X THE RISK OF STROKE

# USE CASES

## DEEP VENOUS THROMBOSIS



ABOUT 0,1% OF POPULATION / YEAR SUFFERS FROM DVT

### RISK FACTORS

ACQUIRED: OLDER AGE, SURGERY, PREGNANCY, CANCER-CHEMOTHERAPY, INACTIVITY, OBESITY, PREGNANCY, eETC

INHERITED: PROTEIN C DEFICIENCY, FACTOR V LEIDEN ETC

MIXED: FACTOR VIII-IV-XI LEVELS, PCR, FIBRINOGEN, HYPERHOMOCYSTEINEMIA ETC

# USE CASES

## CARDIAC MECHANICAL VALVE



ABOUT 0,5% OF ELDER PEOPLE LIVES WITH VALVE CARDIAC PROSTHESIS

RISK FACTORS

VALVULOPATHY, OBESITY, HYPERTENSION



# MEDICAL THERAPY & STROKE

MANY MEDICAL DOCTORS PRESCRIBE ACETYLSALICYLIC ACID BECAUSE IT IS A SIMPLE THERAPY BUT IT DOESN'T PREVENT STROKE



**ONLY A RIGHT AND BALANCED  
ANTICOAGULANT THERAPY**

HELPS TO PREVENT STROKES

66% AF

80% DVT

75% VMP

# MEDICAL THERAPY

WARFARIN (e.g. COUMADIN ®) and ACENOCOUMAROL (e.g. SINTROM ®)

ARE THE MOST COMMONLY USED  
ANTICOAGULANT AGENTS WORLDWIDE

THEY NEED A ROUTINE  
ANTICOAGULATION MONITORING  
AVERAGE EVERY 15 DAYS

WHERE  
A FREQUENT INR MONITORING INCREASES THE TIME IN THERAPEUTIC RANGE  
e.g. IN UK ESTABLISHED A ONLY 5% OF IMPROVEMENT OF THE THERAPEUTIC  
RANGE WOULD PREVENT 500 STROKES/YEAR

# MEDICAL THERAPY

*NEWER AGENTS AS:*

DIABIGATRAN (e.g. PRADAXA®), APIXABAN (e.g. ELIQUIS®), RIVAROXABAN (e.g. XARELTO®)

ARE VERY EXPENSIVE DRUGS PREPARED TO BE USED WITHOUT  
A ROUTINE ANTICOAGULATION MONITORING

CLINICAL EXPERIENCE: THEY ARE NOT SO REALLY SURE

LACK OF REVERSAL AGENTS, INABILITY TO USE IN PATIENTS WITH RENAL OR HEPATIC IMPAIRMENT, LIMITED EXPERIENCE WITH  
DRUG-DRUG AND DRUG-DISEASE INTERACTION, LACK OF AVAILABLE TESTS TO QUANTIFY THEIR EFFECTS

REQUIRE ROUTINE MONITORING AS THE OLD THERAPY

(AIFA 11/09/2013)

(PT 2014 Jan;39(1)54-64)

# ANTICOAGULATION RIGHT MEDICAL THERAPY

## INR

“INTERNATIONAL NORMALIZED RATIO”

IS A NUMBER OBTAINED FROM BLOOD  
EXAM ON THE PROTHROMBIN TIME (PT)



IT IS NEEDED  
FOR THE RIGHT DOSE THERAPY

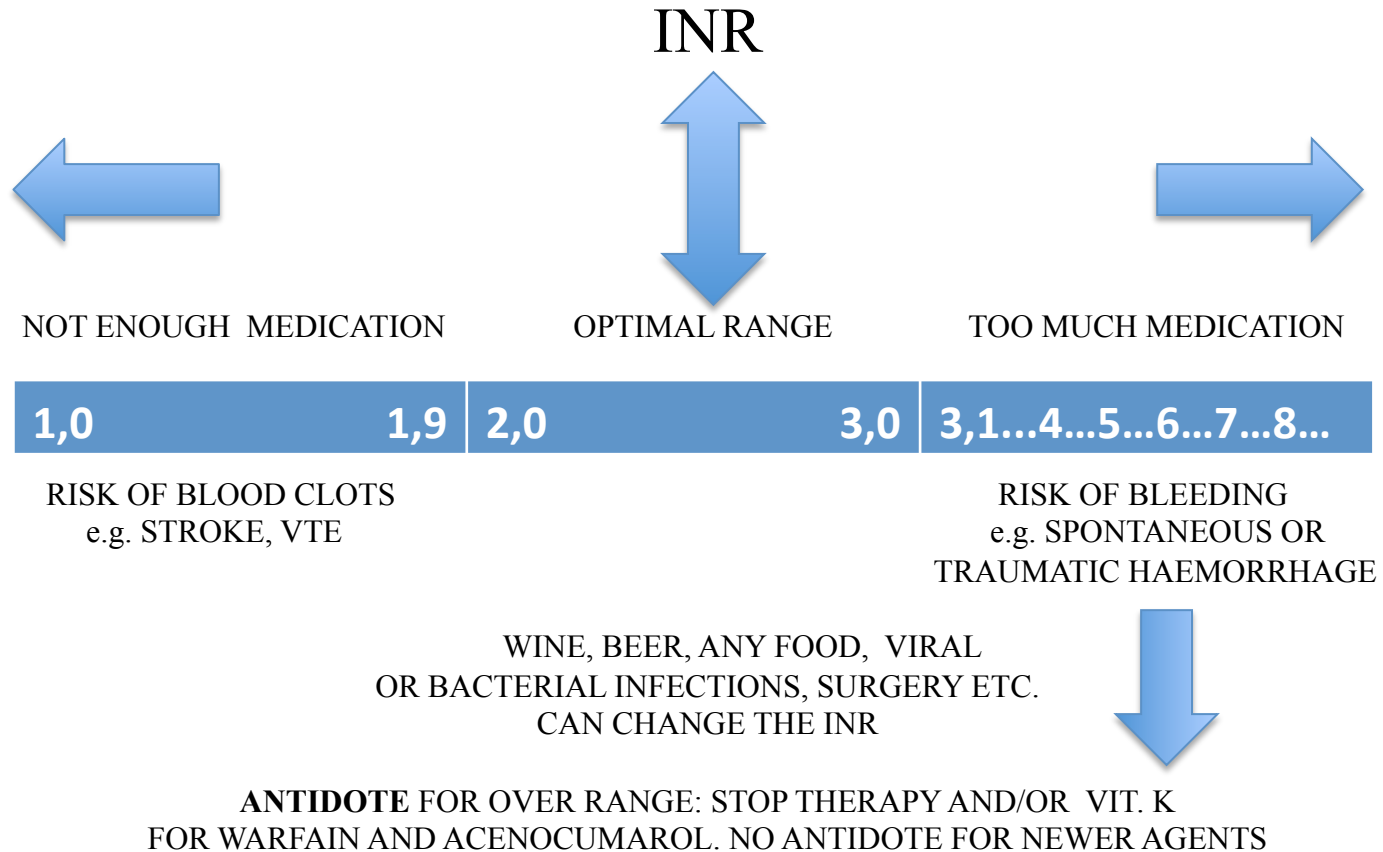
THE THERAPEUTIC RANGE  
IS USUALLY FROM

2,0 TO 3,0

THE OPTIMAL INR IS 2,5-2,7

(OVER RANGE STOP THERAPY, WITH WARFARIN AND ANTIDOTE FOR OVER RANGE VIT. K)

# ANTICOAGULATION RIGHT MEDICAL THERAPY



# THERAPIES DEFAULT

## **UNIQUE ASSUMPTION: A RIGHT AND CONTROLLED ANTICOAGULANT THERAPY**

HELPS TO PREVENT ISCHEMIC-BLEEDING STROKES

66% AF

80% DVT

75% VMP

AND

HOSPITALIZATION, CONSULTATIONS, RIHAB, DAYS OF LOST WORK, MORTALITY  
**SO SAVES COSTS**

ONLY 50% OF PEOPLE IS IN RIGHT PROTOCOLLED THERAPY BECAUSE:  
PATIENTS ARE NOT SO WELL INFORMED  
MANY PATIENTS HATE BLOOD DRAW EXAM  
LOGISTICS DISCOURAGE THERAPIES

AND

GENERAL DOCTORS OFTEN PREFER ACID ACETYLSALICYLIC OR ANTIHARRYTMIC DRUGS:  
THEY NEED LESS CONTROLS BUT THIS IS A VERY DANGEOROUS STYLE AGAINST COMMUNITY

# PICTURE OF ITALY

**IN ITALY > 800.000 PEOPLE  
COULD BE IN OAC THERAPY  
FOR AF, DVT, VMP OR MORE DISEASES**

FOR THE RIGHT THERAPEUTIC PROTOCOL  
THEY COULD NEED AT LEAST

**19.200.000**

BLOOD PT-INR EXAMS / YEAR

(800.000 X 2 / MONTH X 12 MONTHS)

# COAGU-CHEK® FROM ROCHE™



**MEDICAL DEVICE FDA APPROVED  
ALLOWS TO MAKE A SIMPLE AND SAFE EXAM  
LIKE THE GLYCAEMIA ONE  
FEW SECONDS FOR THE ANSWER**

**AT NOW WE RECEIVE THE DATA ON THE TELECOM ITALIA™  
PLATFORM “HOMEDOCTOR”**



# THE FUTURE WE WANT



SHARE 1.500 MEDICAL DEVICES  
TO PHARMACIES  
AND CLOSED COMMUNITIES



WHERE PEOPLE UNDERGOES TO THE SIMPLE BLOOD EXAM  
RECEIVING IN 2 MINUTES THE PRESCRIPTION  
AS PDF WRITTEN AND SIGNED REPORT  
FOR THE NEXT DAYS THERAPY / CONTROLS

# THE TELEMEDICINE MODEL

DOCTORS SPECIALIZED IN HAEMATOLOGY  
RECEIVING THE DATA (24/7 FOR EMERGENCIES)

AND PRESCRIBING THE RIGHT BALANCED THERAPY

INR IS A NUMBER  
SO SW REDUCES TIMING FOR THE REPORTS



RED LIGHT: NEED TO INCREASE / STOP THERAPY OR VIT K

YELLOW LIGHT: INCREASE THE MONITORING TIME

GREEN LIGHT: RIGHT DOSE

# TELEMEDICINE'S MORE MODELS

INTRODUCING MONITORING  
PROTOCOLS IN NEWEST TELEMEDICINE

OPENING BODY GUARDIAN  
AS PERIODIC CONTROL IN PEOPLE  
SUFFERING FROM AF ADJUSTING THERAPIES



ASKING REFUND FROM NHS  
(ACTUALLY € 70/DAY AS HOLTER)

&

OPENING BLOOD PRESSURE DEVICE  
AS HIGH RISK FACTOR  
ALMOST IN AF ELDER PEOPLE



# THE TELEMEDICINE BUSINESS

## CONTROLLED MONITORING OF PEOPLE IN OAC DRUGS

**ITALY - MINISTRY OF HEALTH**



**REFUND FOR DRAW EXAM  
OR EQUIPOLLENT**



**PLUS FEE / PATIENT / EXAM**



**ITALIAN NHS SAVING > 1.5 BILL / Y**



**TO BE DUPLICATED WORLDWILDE**



# BIBLIOGRAPHY

Stroke Research and Treatment. Volume 2012 (2012), Article ID 436125, 11 pages

EHRA Practical Guide on the use of new oral anticoagulants in patients with non valvular atrial fibrillation: executive summary. European Heart J, doi:10.1093/eurheartj/ehs134, 2013

<http://www.agenziafarmaco.gov.it/it/content/nota-informativa-importante-sui-nuovi-anticoagulanti-orali-eliquis-pradaxa-xarelto-11092013>

Thromb Haemost. 2014 Apr 1;111(6). [Epub ahead of print]

Feasibility and cost effectiveness of stroke prevention through community screening for atrial fibrillation using iPhone ECG in pharmacies. The SEARCH-AF study.

Lowres N, Neubeck L, Salkeld G, Krass I, McLachlan AJ, Redfern J, Bennett AA, Briffa T, Bauman A, Martinez C, Wallenhorst C, Lau JK, Brieger DB, Sy RW, Freedman SBI.

Eur J Neurol. 2013 Jul;20(7):1094-100. doi: 10.1111/ene.12143. Epub 2013 Apr 8. Cost of stroke in France.

Chevreul K1, Durand-Zaleski I, Gouépo A, Fery-Lemonnier E, Hommel M, Woimant F.

New Zealand clinical guidelines for stroke management, 2010

Am J Med. 2014 Apr;127(4):e15-6. doi: 10.1016/j.amjmed.2013.06.002. Atrial fibrillation and stroke: epidemiology. Reiffel JA.

P T. 2014 Jan;39(1):54-64. New oral anticoagulants for atrial fibrillation: are they worth the risk? Shafeeq H, Tran TH.

Thromb Haemost. 2014 Apr 1;111(6).

Feasibility and cost effectiveness of stroke prevention through community screening for atrial fibrillation using iPhone ECG in pharmacies. The SEARCH-AF study.

Lowres N, Neubeck L, Salkeld G, Krass I, McLachlan AJ, Redfern J, Bennett AA, Briffa T, Bauman A, Martinez C, Wallenhorst C, Lau JK, Brieger DB, Sy RW, Freedman SBI.

[http://www.roche.com/130903\\_jamescreeden.pdf](http://www.roche.com/130903_jamescreeden.pdf) How diagnostics can help alleviate healthcare cost burden James Creeden, Chief Medical Officer Roche Professional Diagnostics

# BIBLIOGRAPHY

- R I Med J (2013). 2014 May 1;96(3):27-30. Advances in Stroke Over the Past Decade. [Silver B.](#)
- Neurol Clin Pract. 2014 Apr;4(2):96-98. Stroke prevention in atrial fibrillation: Commentary regarding the AAN's evidence-based guideline update. [Hart RG, Eikelboom JW.](#)
- J Cardiovasc Transl Res. 2014 May 1. Left Atrial Appendage Devices for Stroke Prevention in Atrial Fibrillation. [Hussain SK1, Malhotra R, Dimarco JP.](#)
- J Am Geriatr Soc. 2014 May 1. doi: 10.1111/jgs.12799. New Oral Anticoagulants in Elderly Adults: Evidence from a Meta-Analysis of Randomized Trials. [Sardar P1, Chatterjee S, Chaudhari S, Lip GY.](#)
- Rev Esp Cardiol (Engl Ed). 2013 Jul;66(7):545-52. doi: 10.1016/j.rec.2013.03.003. Epub 2013 May 31. Prevalence of Undiagnosed Atrial Fibrillation and of That Not Being Treated With Anticoagulant Drugs: the AFABE Study. [Clua-Espuny JL1, Lechuga-Duran I2, Bosch-Princep R3, Roso-Llorach A3, Panisello-Tafalla A2, Lucas-Noll J2, López-Pablo C3, Queralt-Tomas L2, Giménez-García E4, González-Rojas N5, Gallofré López M6.](#)
- F1000Prime Rep. 2014 Apr 1;6:22. eCollection 2014. Management of atrial fibrillation. [Vergara P, Della Bella P.](#)
- Curr Med Res Opin. 2014 May 2. Is rivaroxaban associated with lower inpatient costs compared to warfarin among patients with non-valvular atrial fibrillation? [Laliberté F1, Pilon D, Raut MK, Nelson WW, Olson WH, Germain G, Schein JR, Lefebvre P.](#)
- Ther Clin Risk Manag. 2014 Mar 22;10:197-205. eCollection 2014. Rivaroxaban as an oral anticoagulant for stroke prevention in atrial fibrillation. [Jurpie AG.](#)
- Continuum (Minneap Minn). 2014 Apr;20(2 Cerebrovascular Disease):309-22. doi: 10.1212/01.CON.0000446103.82420.2d. Evaluation and prevention of cardioembolic stroke.
- JMIR Res Protoc. 2014 Apr 1;3(2):e21.
- Dabigatran Versus Warfarin After Bioprosthesis Valve Replacement for the Management of Atrial Fibrillation Postoperatively: Protocol. [Duraes AR1, Roriz PD, Bulhoes FV, Nunes BD, Muniz JQ, Neto IN, Fernandes AM, Reis FJ, Camara EJ, Junior ED, Segundo DT, Silva FP, Aras R.](#)

# BIBLIOGRAPHY

- P T. 2014 Jan;39(1):54-64. New oral anticoagulants for atrial fibrillation: are they worth the risk? [Shafeeq H, Tran TH.](#)
- Am J Med. 2014 Apr;127(4):e15-6. doi: 10.1016/j.amjmed.2013.06.002. Atrial fibrillation and stroke: epidemiology. [Reiffel JA.](#)
- Am J Med. 2014 Apr;127(4):e15. doi: 10.1016/j.amjmed.2013.06.001. New versus traditional approaches to oral anticoagulation in patients with atrial fibrillation. [Reiffel JA.](#)
- Expert Rev Cardiovasc Ther. 2014 Apr;12(4):403-6. doi: 10.1586/14779072.2014.896196. Atrial fibrillation and stroke prevention: brief observations on the last decade [Lip GY.](#)
- Can Fam Physician. 2014 Mar;60(3):e173-9. Atrial fibrillation anticoagulation care in a large urban family medicine practice. [Valentinis A1, Ivers N, Bhatia S, Meshkat N, Leblanc K, Ha A, Morra D](#)
- Neurology. 2014 Feb 25;82(8):716-24. doi: 10.1212/WNL.0000000000000145. Summary of evidence-based guideline update: prevention of stroke in nonvalvular atrial fibrillation: report of the Guideline Development Subcommittee of the American Academy of Neurology. [Culebras A1, Messé SR, Chaturvedi S, Kase CS, Gronseth G.](#)
- Thromb J. 2014 Feb 18;12(1):5. doi: 10.1186/1477-9560-12-5. Warfarin and atrial fibrillation: from ideal to real the warfarin affaire. [Molteni M1, Cimminiello C.](#)