

# Recente letteratura sulla validità del self-testing e self-management della terapia con antivitamina K (AVK)

Francesco Dentali, Dipartimento di Medicina Clinica,  
Università dell'Insubria Varese,

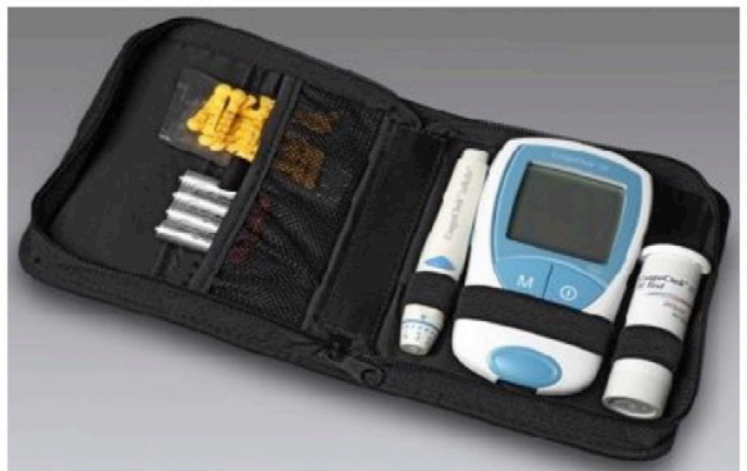
*Il sottoscritto Francesco Dentali*

*ai sensi dell'art. 3.3 sul Conflitto di Interessi, pag. 17 del Reg. Applicativo dell'Accordo Stato-Regione del 5 novembre 2009,*

*Dichiara che negli ultimi due anni ha avuto rapporti diretti di finanziamento con i seguenti soggetti portatori di interessi commerciali in campo sanitario:*

- Bayer
- Sanofi
- BMS/Pfizer,
- Boehringer
- Alfa Wassermann
- Daiichi
- IL

# Point of Care Testing



## Il paziente...

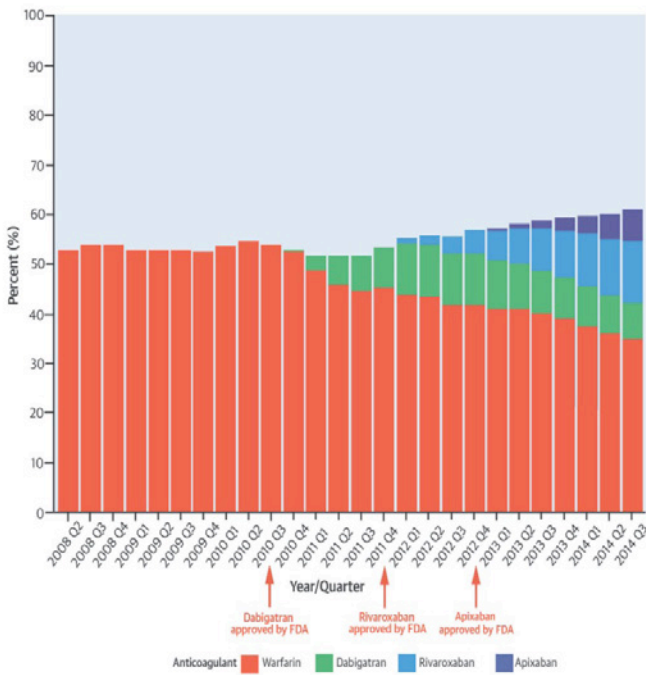


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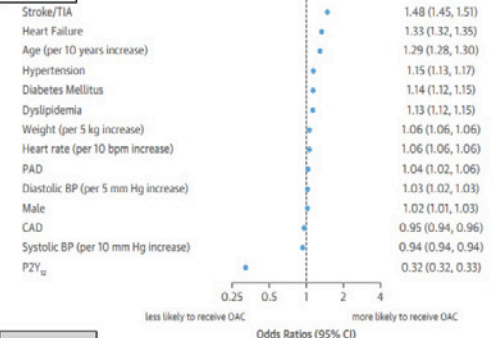
“ ANTICOAGULAZIONE | Attualità cliniche e di laboratorio. Aspetti sociali ”

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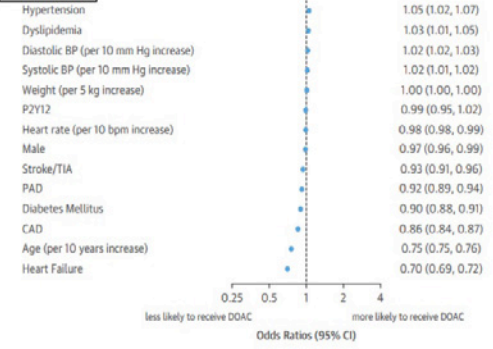
# Influence of DOAC on Rates of OAT for AF



## OAT

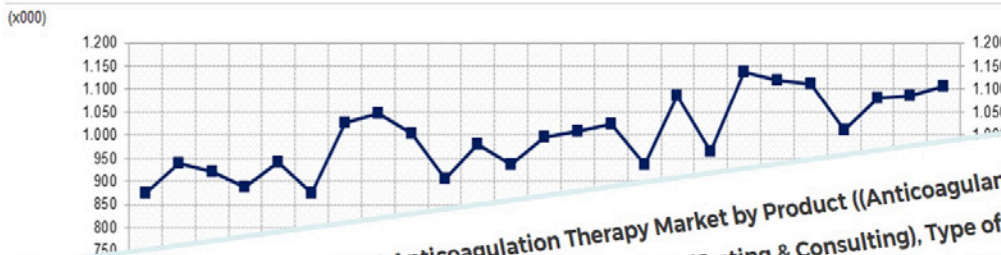


## NOAC

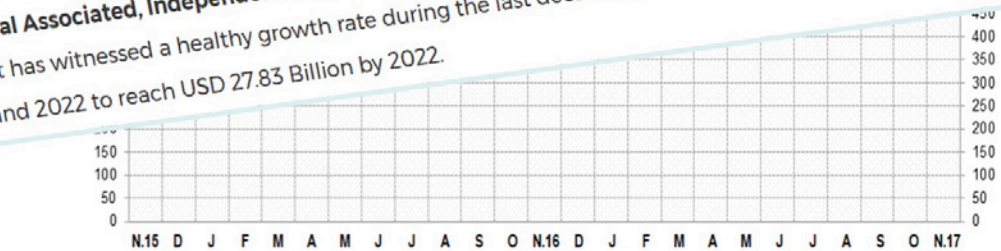


Marzec LN, et al. J Am Coll Cardiol 2017;69:2475

## ITALY\_ OA Unfactored Market: VKA vs NOA Pack EQ (RETAIL, HOSPITAL & DPC – MONTHLY Data) Novembre 2017



According to a new market research report "US Anticoagulation Therapy Market by Product ((Anticoagulants Drugs (NOACs, Warfarin)), PT/INR Devices (In-Office, Home Testing)), Service Type (Testing & Consulting), Type of Clinic (Hospital Associated, Independent & Pharmacy-based) - Forecast to 2022", published by MarketsandMarkets™, the market has witnessed a healthy growth rate during the last decade and is expected to grow at a CAGR of 8.5% between 2017 and 2022 to reach USD 27.83 Billion by 2022.



	N	15	D	J	F	M	A	M	J	J	A	S	O	N.16	D	J	F	M	A	M	J	J	A	S	O	N.17
VKA	694	628	614	571	597	532	650	659	592	540	665	522	554	564	551	485	561	497	575	561	550	499	502	496	511	
NOA	283	310	307	317	344	342	377	389	410	365	416	414	440	446	473	452	525	467	562	559	562	513	578	590	597	
TOT OA	876	939	921	888	942	874	1027	1048	1003	905	981	936	995	1010	1024	937	1086	965	1137	1119	1112	1012	1080	1086	1107	
±% L.Y.		+12.2	+12.2	+4.2	+17.0	+8.2	+2.5	+15.5	+12.5	+3.4	+16.8	+9.2	+6.0	+13.5	+7.5	+11.2	+5.5	+15.4	+10.3	+10.7	+6.8	+10.8	+11.8	+10.1	+16.0	+11.3

Source: IMS

# Quali pazienti ancora in Warfarin nel 2018?

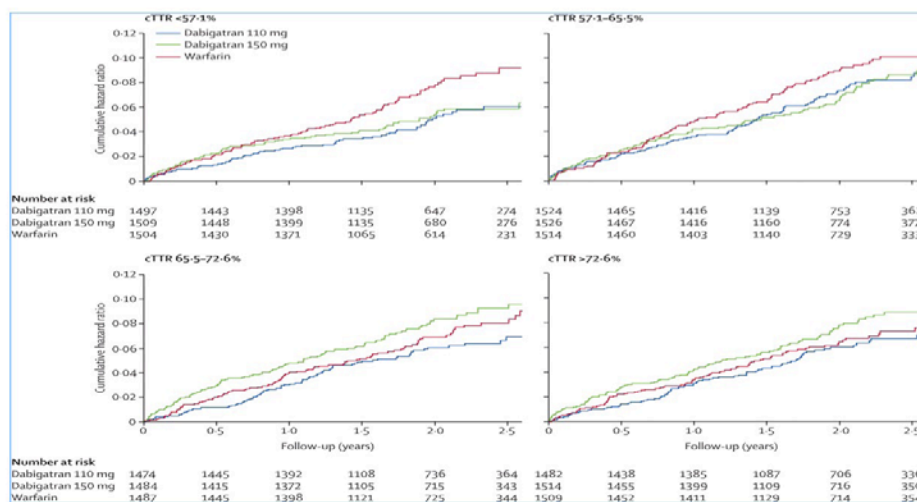
- Valvuloprotresi meccaniche
- Insufficienza renale grave
- Intolleranti ai DOAC
- DOAC inefficaci
- Scelta del paziente
- ...



## Efficacy and safety of dabigatran compared with warfarin at different levels of international normalised ratio control for stroke prevention in atrial fibrillation: an analysis of the RE-LY trial



### Major Bleeding



Wallentin et al Lancet 2010



# Efficacy and safety of dabigatran compared with warfarin at different levels of international normalised ratio control for stroke prevention in atrial fibrillation: an analysis of the RE-LY trial



## Bleeding

	110 mg dabigatran			150 mg dabigatran			Warfarin			110 mg dabigatran vs warfarin		150 mg dabigatran vs warfarin	
	Patients (n)	Events	Rate per 100 person-years	Patients (n)	Events	Rate per 100 person-years	Patients (n)	Events	Rate per 100 person-years	HR (95% CI)	p (interaction)	HR (95% CI)	p (interaction)
<b>Major bleeding</b>													
<57.1%	1497	68	2.36	1509	74	2.54	1504	101	3.59	0.65 (0.48-0.89)	..	0.71 (0.52-0.96)	..
57.1-65.5%	1524	103	3.38	1526	102	3.33	1514	124	4.13	0.82 (0.63-1.06)	..	0.81 (0.62-1.05)	..
65.5-72.6%	1474	84	2.82	1484	113	3.80	1487	101	3.40	0.83 (0.62-1.11)	..	1.13 (0.87-1.48)	..
>72.6%	1482	82	2.81	1514	108	3.60	1509	93	3.11	0.90 (0.67-1.21)	0.50	1.16 (0.88-1.54)	0.03
<b>Major gastrointestinal bleeding</b>													
<57.1%	1497	33	1.15	1509	44	1.51	1504	40	1.42	0.81 (0.51-1.29)	..	1.08 (0.70-1.66)	..
57.1-65.5%	1524	51	1.67	1526	54	1.76	1514	48	1.60	1.05 (0.71-1.56)	..	1.11 (0.75-1.63)	..
65.5-72.6%	1474	40	1.34	1484	73	2.46	1487	33	1.11	1.22 (0.77-1.94)	..	2.26 (1.50-3.40)	..
>72.6%	1482	37	1.27	1514	52	1.73	1509	26	0.87	1.46 (0.89-2.41)	0.36	2.00 (1.25-3.21)	0.019
<b>Total bleeding</b>													
<57.1%	1497	351	12.20	1509	420	14.42	1504	466	16.56	0.71 (0.62-0.82)	..	0.89 (0.78-1.01)	..
57.1-65.5%	1524	428	14.04	1526	486	15.88	1514	570	18.96	0.71 (0.63-0.80)	..	0.82 (0.73-0.93)	..
65.5-72.6%	1474	479	16.07	1484	512	17.24	1487	557	18.74	0.85 (0.75-0.96)	..	0.92 (0.81-1.03)	..
>72.6%	1482	468	16.03	1514	542	18.08	1509	555	18.55	0.84 (0.74-0.95)	0.076	1.00 (0.89-1.12)	0.15

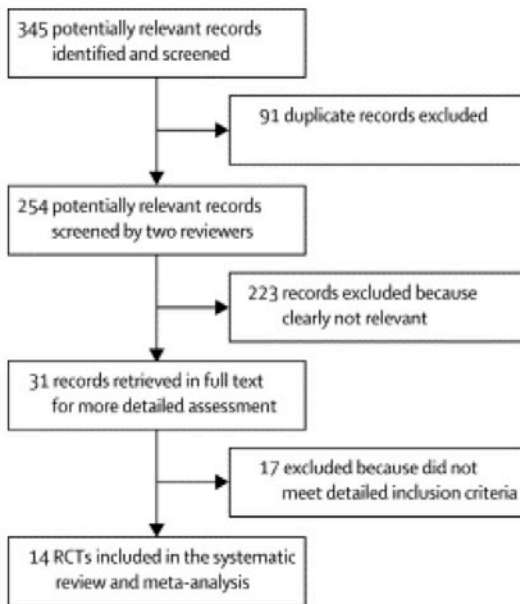
HR-hazard ratio.

Wallentin et al Lancet 2010

## POC: Obiettivi x il paziente e il medico

- Numero non inferiore di eventi tromboembolici
- Numero non inferiore di eventi emorragici
- Numero non inferiore di morti

# Meta-Analisi

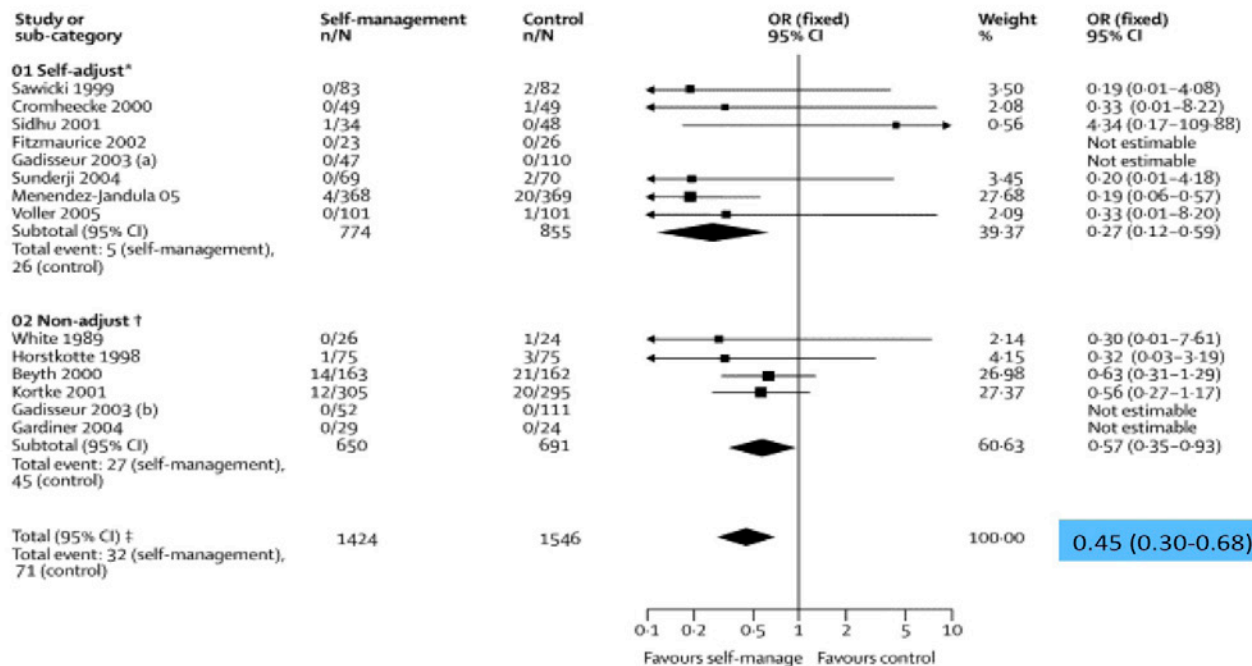


Inclusion criteria	Duration of study (months)	Mean age (years)	Numbers analysed		Control-group intervention	Education and intervention for self-monitoring group	
			Control (n=1585)	Intervention (n=1464)			
White 1989, USA*	Inpatients receiving intravenous heparin with a planned duration of warfarin therapy of at least 8 weeks*	2	50	24	26	Specialist anticoagulation clinic care. Managed by nurse specialists	Patients managed directly by general internists
Horstkotte 1998, Germany*	Outpatients with isolated aortic or mitral valve replacement with the St Jude Medical prosthesis†	N/A	N/A	75	75	Managed by home physician	Standardised training, measured INR twice a week, and contacted coagulation clinic by phone
Sawicki 1999, Germany*	Any indication for anticoagulation and on life long treatment†	6	55	82	83	Twice-monthly adjustment by family doctor	Three educational sessions. Self adjusted
Beyth 2000, USA*	Inpatients aged >65 years receiving 10 000 units or more of intravenous heparin†	6	75	162	163	Managed by primary care physician as per usual practice	1-h education session, patients phoned results to coach who made recommendations
Cromheecke 2000, Netherlands*	Long-term anticoagulation, at least 6 months treatment†	3	42	49	49	Testing at intervals of 1-2 weeks and managed by a specialised anticoagulation service	Two educational sessions, self adjusted
Kortke 2001, Germany*	Permanent oral anticoagulation after mechanical heart valve surgery†	24	62.5	295	305	Managed by primary care physician as per usual practice	Trained in self-monitoring 6-11 days after operation
Sidhu 2001, UK*	Permanent oral anticoagulation after mechanical heart valve surgery performed by one surgeon†	24	61	48	34	Managed by family doctor as per usual practice	Two educational sessions, doctor availability to receive calls, patients self-adjusted as per protocol
Fitzmaurice 2002, UK*	Long-term anticoagulation at least 6 months treatment, with satisfactory INR control (INR within 0.5 of target value 60% of the time)†	6	63	26	23	Managed by primary care physician as per usual practice	Two educational workshops, daytime access to medical care. Self adjusted warfarin according to a dosing algorithm
Gadisseur 2003, Netherlands*	Long term oral anticoagulation at least 3 months treatment†	6	57	221	99	Routine care by anticoagulation clinic physicians	Three educational sessions. Self adjustment confirmed by telephone
Gardiner 2004, UK*	At least 8 months of oral anticoagulation treatment with a previous record of good compliance†	6	58	24	29	Testing every 4 weeks or more often if indicated by anticoagulation clinic staff	Two educational sessions, 1 week apart
Khan 2004, UK*	At least 12 months treatment with warfarin patients with AF. Age >65 years†	6	Median 73	39	40	Managed by anticoagulation clinic, review according to INR	2-h education session, study coordinator liaised by phone and gave advice on dosage for next 7 days
Sunderji 2004, Canada*	Receiving warfarin for at least 1 month and required anticoagulation for at least 1 year†	8	60	70	69	Managed by primary care physician as per usual practice	Two educational sessions, self adjusted using a nomogram
Menendez-Jandula 2005, Spain*	Any indication of anticoagulation and at least 3 months therapy†	11-8	66	369	368	Testing at least every 4 weeks and managed by a haematologist at an anticoagulation clinic	Two educational sessions, taught by nurse. Card system to aid self adjustment
Voller 2005, Germany*	Long-term oral anticoagulation in patients with non-valvular AF†	5	64	101	101	Managed by family doctor as per usual practice	Standard training course of three sessions

AF=atrial fibrillation. \*Coagumcheck monitor. †Coagucheck system. ‡Pro time microcoagulation system.

Heneghan et al Lancet 2006

## Eventi Tromboembolici



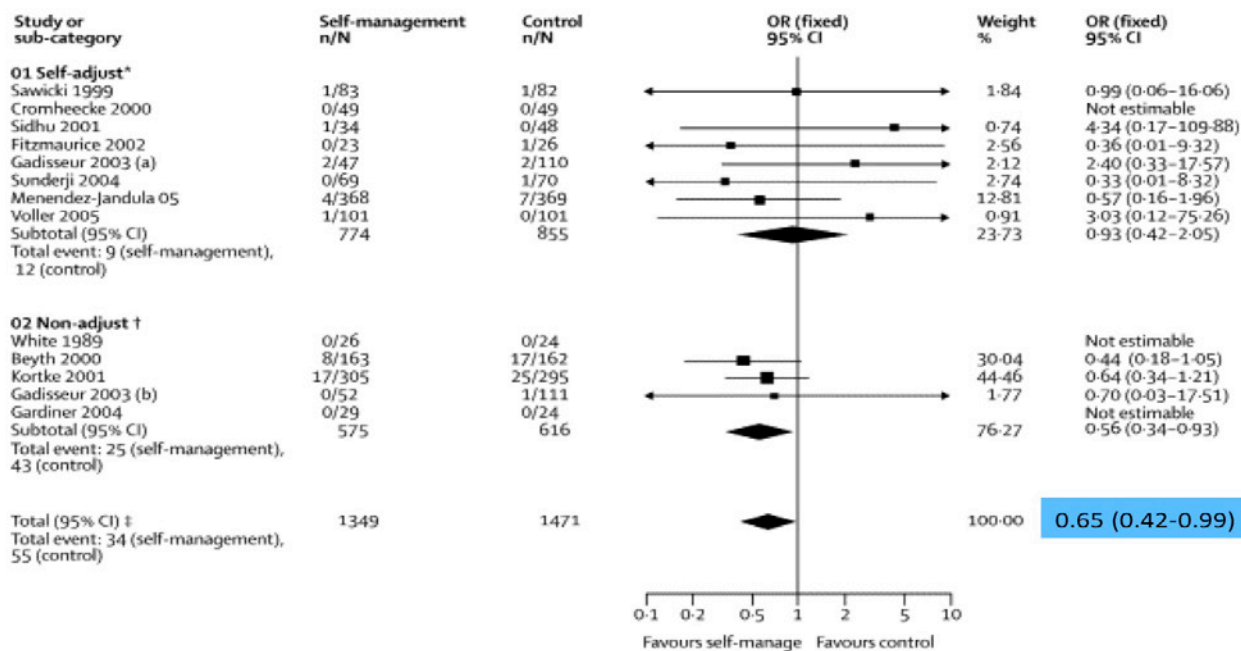
Heneghan et al Lancet 2006

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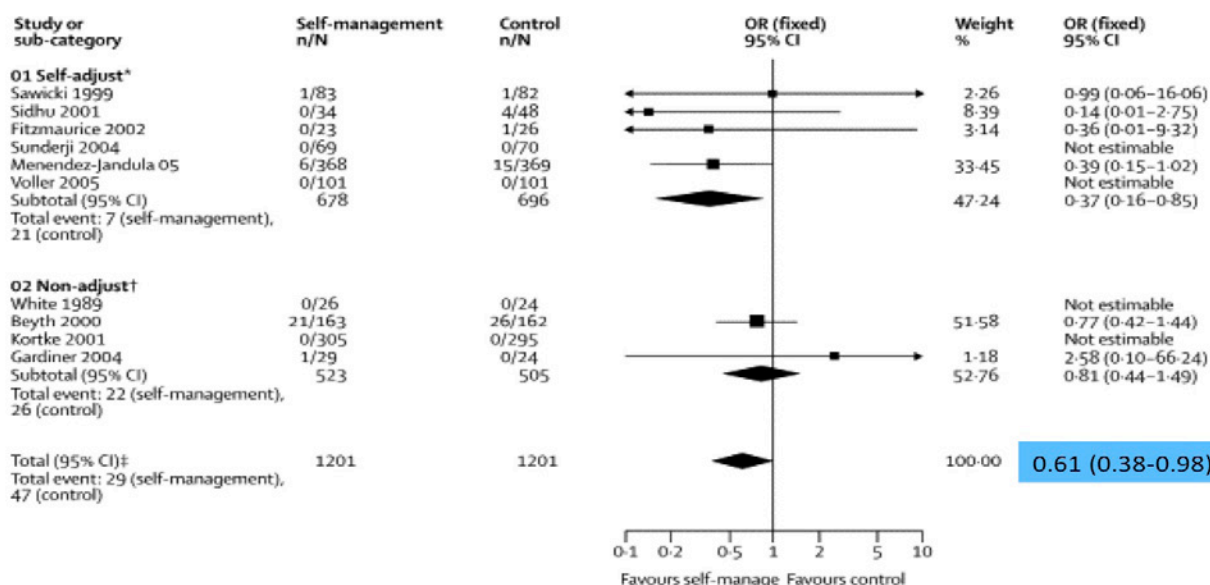
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# Eventi Emorragici



Heneghan et al Lancet 2006

# Mortalità



Heneghan et al Lancet 2006



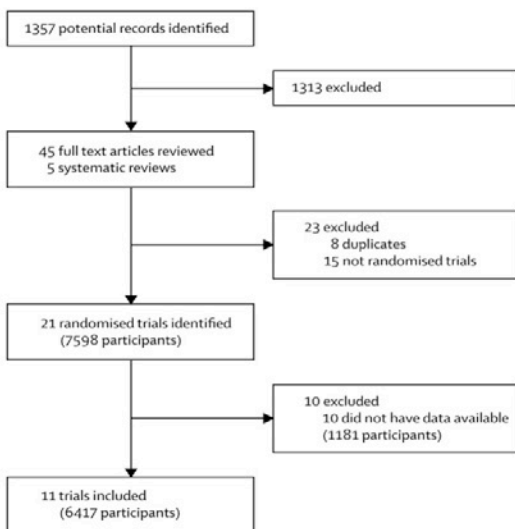
CARE MANAGEMENT STRATEGIES

# Self-monitoring and self-dosing of oral anticoagulation improves survival <sup>☆</sup>

James D Douketis, Debbie Singh



## Individual Patient Meta-Analysis

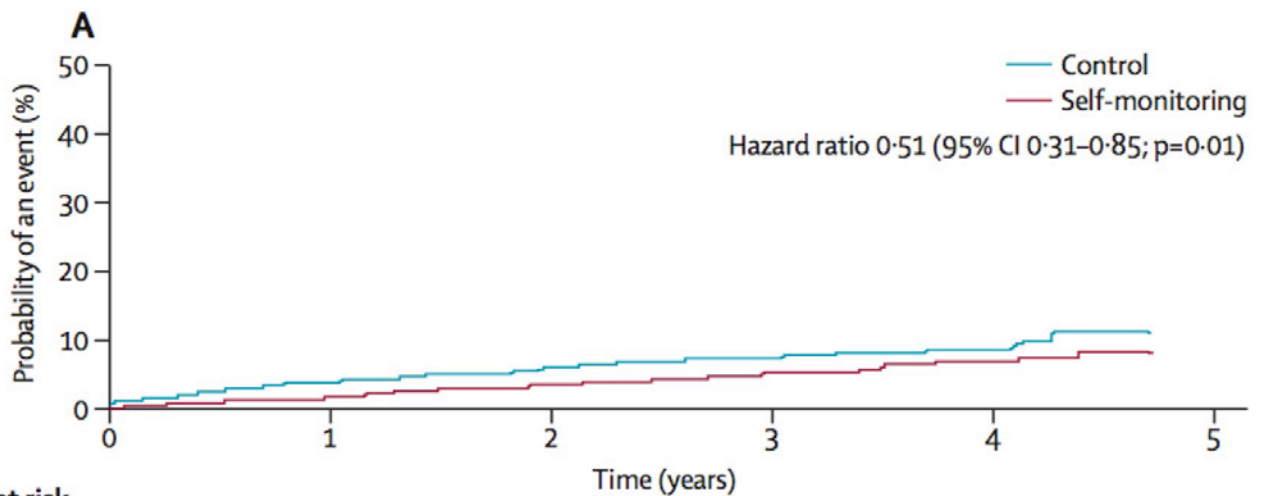


	Country	Dates of recruitment	Year of publication of primary results	Study duration (months)	Age range, years (mean)	Total number of patients	Female	Atrial fibrillation	Mechanical valve	Other	Self management	Type of control group care
Beyth et al <sup>1*</sup>	USA	1992-95	2000	6	65-94 (74.7)	325 (5%)	184 (57%)	54 (17%)	36 (11%)	235 (72%)	No	Primary Care
Cromheecke et al <sup>2†</sup>	Holland	1998	2000	3	22-71 (42.3)	49 (1%)	21 (43%)	11 (22%)	23 (47%)	15 (31%)	Yes	Anticoagulation clinic
Koertke et al <sup>3†</sup>	Germany	1994-97	2001	24	17-77 (59.7)	930 (14%)	293 (32%)	-	930 (100%)	-	Yes	Primary care
Sunderji et al <sup>4†</sup>	Canada	1998-2002	2004	20	20-85 (60.0)	139 (2%)	41 (29%)	47 (34%)	82 (59%)	10 (7%)	Yes	Primary care
Menéndez-Jándula et al <sup>5†</sup>	Spain	2001-02	2005	12	19-90 (63.5)	737 (11%)	347 (47%)	296 (40%)	285 (39%)	154 (21%)	Yes	Anticoagulation clinic
Völler et al <sup>6†</sup>	Germany	1999-2001	2005	19†	36-85 (64.4)	202 (3%)	53 (26%)	202 (100%)	-	-	Yes	Primary care
Fitzmaurice et al <sup>7†</sup>	UK	2001-02	2005	12	18-87 (65.1)	617 (10%)	217 (35%)	343 (56%)	97 (16%)	177 (29%)	Yes	Both
Christensen et al <sup>8†</sup>	Denmark	2002-03	2006	6	21-78 (50.7)	100 (2%)	33 (33%)	24 (24%)	35 (35%)	41 (41%)	Yes	Both
Siebenhofer et al <sup>9†</sup>	Austria	2002-05	2007	36	60-89 (68.8)	195 (3%)	81 (42%)	89 (46%)	32 (16%)	74 (38%)	Yes	Both
Matchar et al <sup>10†</sup>	USA	2003-06	2010	36	23-90 (67.0)	2922 (46%)	51 (2%)	2236 (77%)	684 (23%)	2 (<1%)	No	Anticoagulation clinic
Kaatz et al <sup>11†</sup>	USA	1998-99	2001	12	30-87 (64.1)	201 (3%)	84 (42%)	86 (43%)	39 (19%)	76 (38%)	No	Anticoagulation clinic
Totals	-	1992-2006	2000-10	-	17-94 (65.0)	6417	1405 (22%)	3388 (53%)	2243 (35.0%)	784 (12%)	-	-

Heneghan et al Lancet 2012



# Eventi Tromboembolici

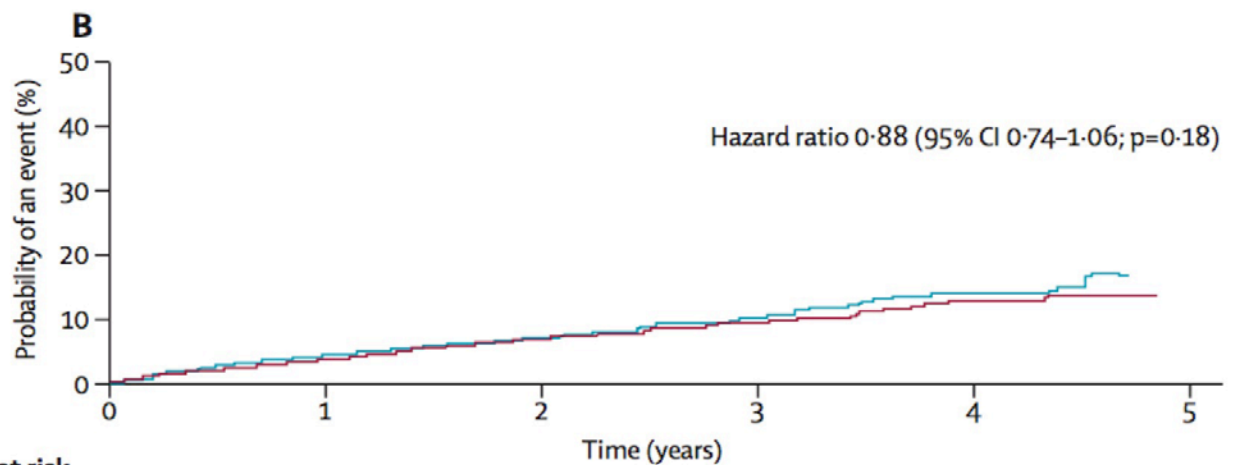


## Number at risk

	0	1	2	3	4	5
Control	3151 (84)	2137 (39)	1214 (17)	771 (7)	275 (4)	0
Self-monitoring	3266 (43)	2232 (38)	1299 (19)	846 (12)	317 (2)	0

Heneghan et al Lancet 2012

# Eventi Emorragici

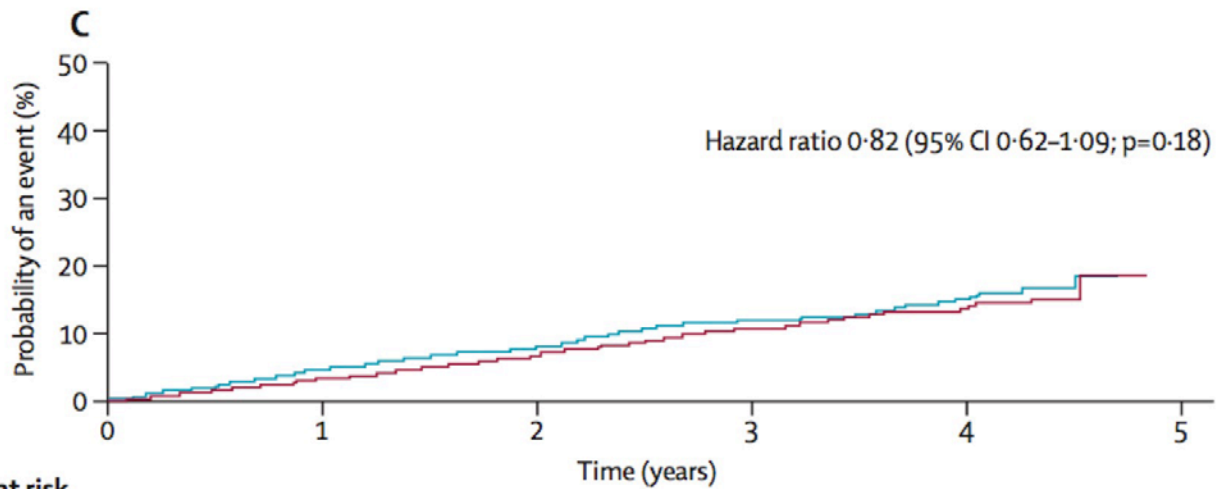


## Number at risk

	0	1	2	3	4	5
Control	3151 (131)	2109 (56)	1189 (30)	742 (24)	251 (2)	0
Self-monitoring	3266 (106)	2189 (64)	1273 (31)	820 (21)	296 (1)	0

Heneghan et al Lancet 2012

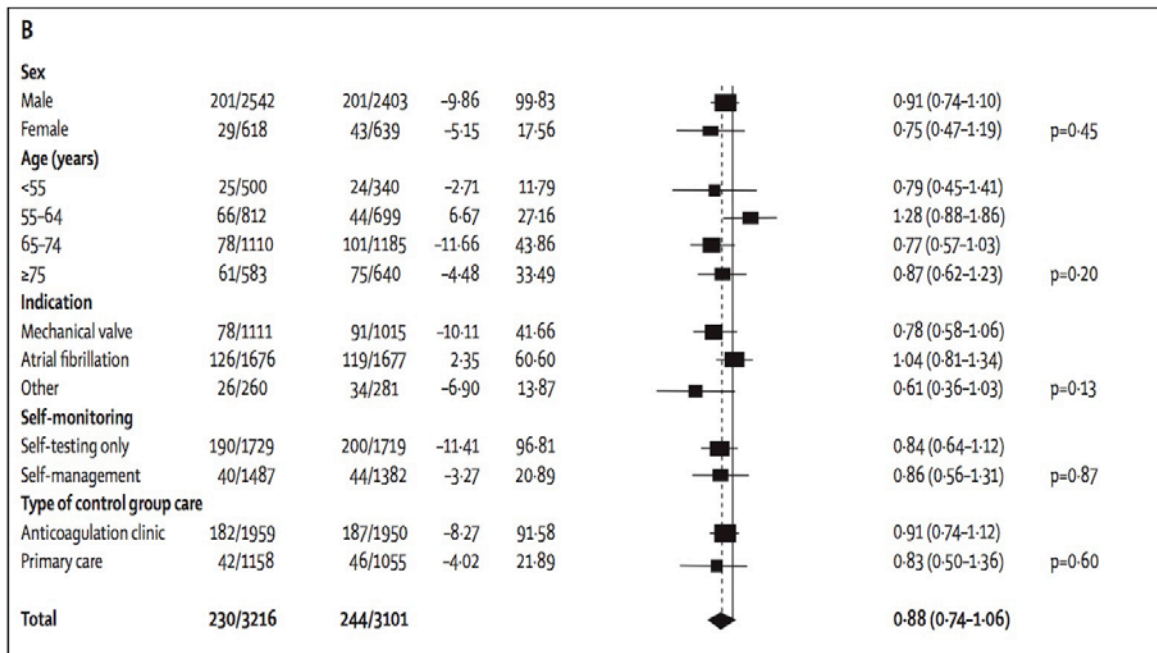
# Mortalità



Number at risk		0	1	2	3	4	5
Control	3151 (130)	2197 (67)	1264 (48)	816 (19)	296 (5)	0	0
Self-monitoring	3266 (96)	2271 (76)	1346 (46)	884 (24)	334 (4)	0	0

Heneghan et al Lancet 2012

# Sottogruppi



Heneghan et al Lancet 2012

# TTR e INR Test

## AF

	Time in therapeutic range			Number of tests		
	Mean difference between self-monitoring and control group (95% CI)	Heterogeneity	p value	Mean difference between self-monitoring and control group (95% CI)	Heterogeneity	p value
7 days	12.25% (8.99 to 15.51)	0	<0.001	0.25 (0.10 to 0.39)	77%	0.001
30 days	6.13% (-0.09 to 12.35)	72%	0.05	2.28 (1.59 to 2.97)	94%	<0.001
6 months	5.13% (-1.13 to 11.40)	79%	0.11	12.71 (9.33 to 16.10)	96%	<0.001
1 year	2.71% (-6.10 to 11.51)	94%	0.55	24.22 (18.40 to 30.04)	93%	<0.001

Data % or % (95% CI).

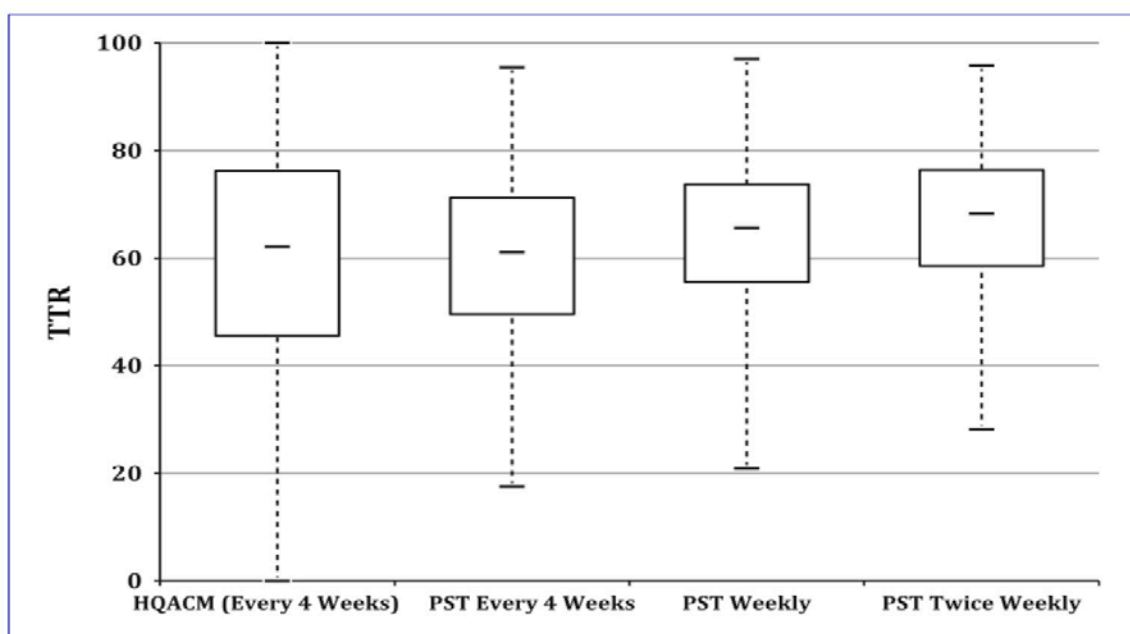
## MHV

	Time in therapeutic range			Number of tests		
	Mean difference between self-monitoring and control group (95% CI)	Heterogeneity	p value	Mean difference between self-monitoring and control group (95% CI)	Heterogeneity	p value
7 days	10.38% (8.56 to 12.20)	0%	<0.001	0.01 (-0.25 to 0.28)	92%	0.91
30 days	3.16% (-4.07 to 10.39)	77%	0.39	1.78 (0.97 to 2.60)	97%	<0.001
6 months	4.40% (-0.86 to 9.67)	79%	0.10	12.03 (7.46 to 16.60)	99%	<0.001
1 year	5.13% (0.97 to 9.28)	57%	0.02	21.74 (13.11 to 30.37)	98%	<0.001

Data % or % (95% CI).

Heneghan et al Lancet 2012

# TTR e INR Test



Matchar et al JTT 2015

# POC e SSN

- Sostenibili in funzione dell'impatto economico sul Sistema Sanitario Nazionale (regionale)

21/01/16 14:56

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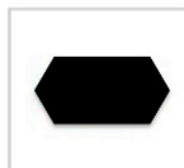
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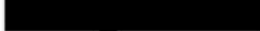
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Risultato PT/INR in 1 minuto con una sola goccia di sangue.

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Prezzo di listino:

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Prezzo Amico:

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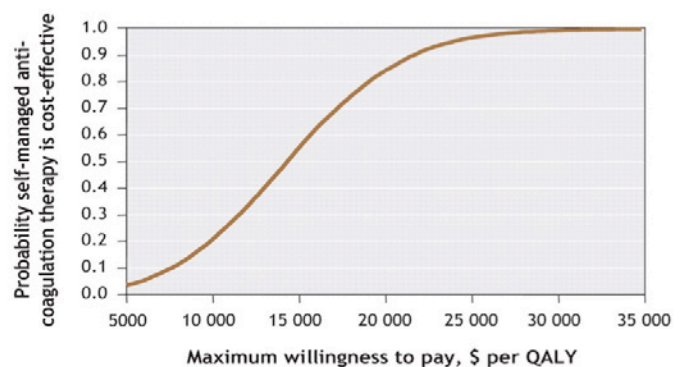
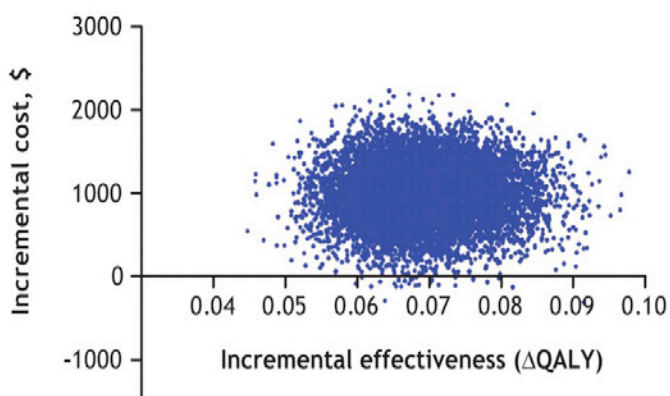
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## Impatto Economico



The cost-effectiveness of self-management was \$14 129 per QALY gained.

Regier et al CMAJ 2006

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# POC x Tutti ?

**bjh** guideline

## An evidence-based review and guidelines for patient self-testing and management of oral anticoagulation

D. A. Fitzmaurice,<sup>1</sup> C. Gardiner,<sup>2</sup> S. Kitchen,<sup>3</sup> I. Mackie,<sup>2</sup> E. T. Murray<sup>1</sup> and S. J. Machin<sup>2</sup> on behalf of The British Society of Haematology Taskforce for Haemostasis and Thrombosis

<sup>1</sup>Department of Primary Care and General Practice, The Medical School, The University of Birmingham, Birmingham, <sup>2</sup>Haemostasis Research Unit, Haematology, UCL, London, and <sup>3</sup>UK NEQAS for Blood coagulation, Rutledge Mews, Sheffield, UK

**bjh** guideline

## An evidence-based review and guidelines for patient self-testing and management of oral anticoagulation

### 9. Guidelines for patient self-testing or -management of oral anticoagulation

Given the relative lack of evidence, the following recommendations are necessarily consensual (evidence level C).

1. Only patients with long-term indications for warfarin therapy should be considered for self-testing or -management. In exceptional circumstances, patients with short-term indications (e.g. first deep vein thrombosis) may be considered for self-testing, however, it should be noted that it can take 2–3 months before a patient becomes fully accustomed to this method of therapy management.

Fitzmaurice et al BJH 2005



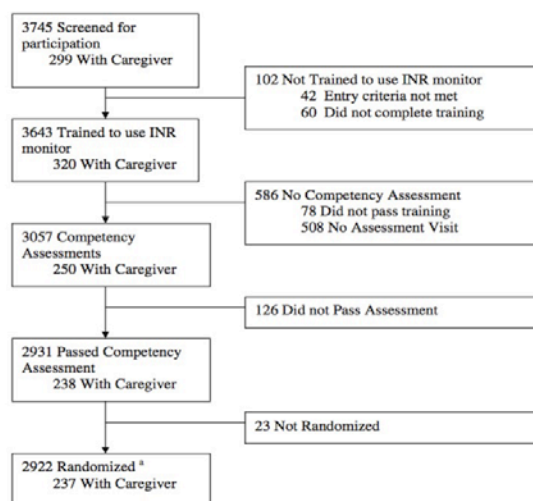
## An evidence-based review and guidelines for patient self-testing and management of oral anticoagulation

2. Only conformite european-marked devices that have undergone acceptable evaluations by an expert, independent body (e.g. the MHRA in the UK) subject to external peer-review, are to be used for self-testing. Discussions should be held with the local haematologist (where appropriate) and with the Trust POC committee before initiating patient self-testing. Local guidelines and procurement rules should also be checked.
3. Patients (or patient carers) must give informed consent to undertake patient self-management. This will include agreement to attend clinic regularly and to record results accurately.
4. Competence to perform an INR must be assessed by a trained healthcare professional prior to allowing home testing.
5. Competence to correctly interpret an INR result must be assessed by a healthcare professional prior to allowing self-management. This must be based on an individualised patient algorithm (Table IV).
6. Previous stability of INR is not a prerequisite to home testing as unstable patients may benefit from increased autonomy and the possibility of increased frequency of testing.
7. Patients considered for self-testing or -management must have a documented INR target in line with accepted guidelines and clinical practice.
8. Contraindications for patient self-testing or -management will include previous non-compliance, in terms of either attendance at clinic or taking of medication.
9. Patients undertaking self-testing or -management must retain contact with a named clinician. This will, in most

- cases, be a consultant haematologist who will be clinically responsible. In all cases the patient's GP and the clinician who initiated the warfarin therapy must be informed.
10. Patients undertaking self-management must be reviewed at least every 6 months by the responsible clinician.
  11. Electronic QC where available should be used each time the monitor is used.
  12. The IQC material should be analysed when introducing a new batch/lot number of test strips or when commencing use of newly delivered test strips (even when they are the same lot number as used previously).
  13. The IQC material should be re-tested if an unexpectedly high or low result occurs.
  14. The IQC should be tested every 1 and 3 monthly, or with each test if the interval between testing exceeds 12 weeks.
  15. Patients who are self-testing should participate in at least one form of EQA, i.e. one of a, b or c below. If a patient has persistent problems the monitor should be assessed in a centre that participates satisfactorily in a formal EQA programme and patient self-testing should be suspended if persistent problems are unresolved. This is the case whichever option is employed.

..... Fitzmaurice et al BJH 2005

## POC x Tutti (ii) ?

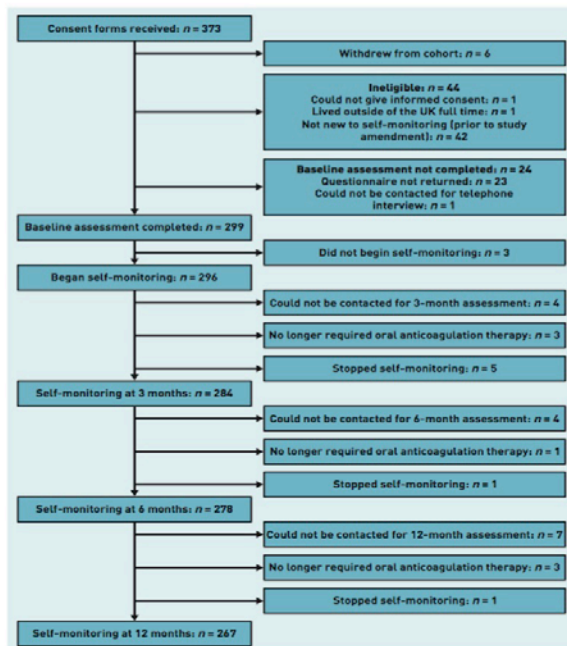


Characteristic	Did not pass assessment (n = 126)	Passed assessment (n = 2931)	Total <sup>a</sup> (n = 3057)	P-value
<b>Tester</b>				
Patient alone	112 (89%)	2693 (92%)	2805 (92%)	0.0013
Patient with help from caregiver	12 (10%)	238 (8%)	250 (8%)	
Missing	2 (2%)	0 (0%)	2 (<1%)	
<b>Integrity of cuvettes (good)</b>	116 (92%)	2835 (97%)	2951 (97%)	0.0002
<b>Qualifying test by tester using patient's device and cuvettes</b>				
Able to perform finger stick (yes)	71 (56%)	2925 (100%)	2996 (98%)	<0.0001
<b>Able to obtain INR independently</b>				
Yes, little or no difficulty	31 (25%)	2837 (97%)	2868 (94%)	<0.0001
Yes, lots of difficulty	36 (29%)	93 (3%)	129 (4%)	
Unable to perform test	52 (41%)	1 (< 1%)	53 (2%)	
Missing	7 (6%)	0 (0%)	7 (<1%)	
<b>Cuvette wastage<sup>b</sup> (yes)</b>	15 (12%)	28 (1%)	43 (1%)	<0.0001
<b>Number of weeks of testing</b>				
2 weeks	106 (84%)	2698 (92%)	2804 (92%)	0.0016
4 weeks	20 (16%)	233 (8%)	253 (8%)	
<b>Competent to proceed to Part 2 (yes)</b>	0 (0%)	2931 (100%)	2931 (96%)	<0.0001
<b>Adverse event since last contact</b>	0 (0%)	0 (0%)	0 (0%)	-

Dolor et al JTT 2015

# Cohort study of Anticoagulation Self-Monitoring (CASM):

a prospective study of its effectiveness in the community



- INR data was received from 92.2% of the 296 who started self-monitoring and analysed for 90.9% of participants.
- Median %TTR was 78.5% (IQR 64.9–88.5).

Ward et al; BJCP 2015

# Cohort study of Anticoagulation Self-Monitoring (CASM):

a prospective study of its effectiveness in the community

## LOGISTIC REGRESSION PREDICTING THOSE WITH >80% TTR

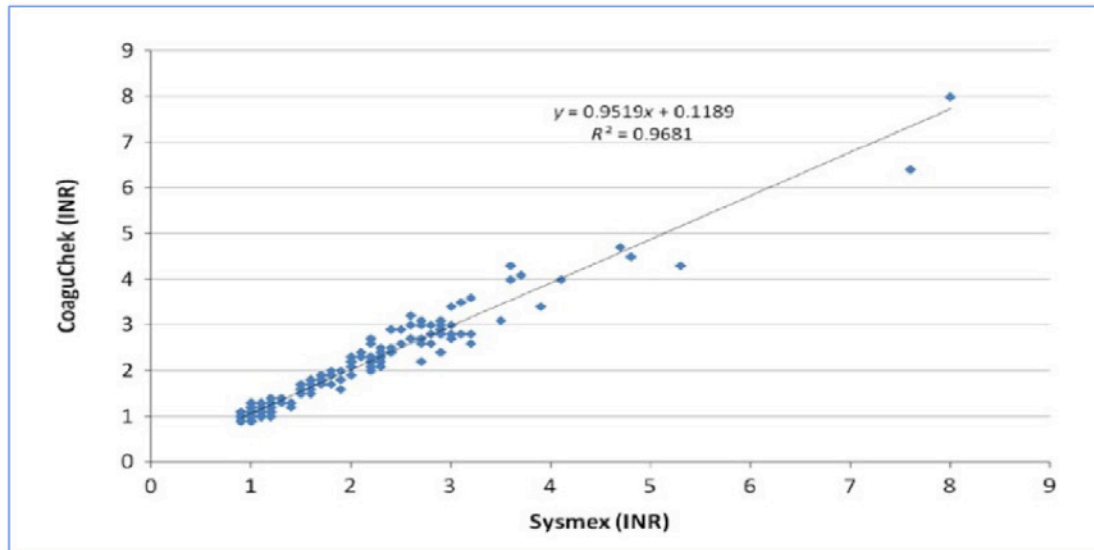
	Odds ratio	95% CI	P-value
<b>All participants (n = 269)</b>			
Age, years <sup>a</sup>	1.024	1.000 to 1.048	0.052
Male <sup>a</sup>	1.320	0.753 to 2.312	0.332
<b>Condition requiring oral anticoagulation therapy<sup>a</sup></b>			
Antiphospholipid syndrome	1.000	–	
Atrial fibrillation	5.231	1.249 to 21.904	0.024
Mechanical heart valve	3.685	0.933 to 14.555	0.063
Thrombosis	4.684	1.209 to 18.149	0.025
Duration of self-monitoring, months <sup>a</sup>	1.004	0.998 to 1.010	0.225
<b>Procedure during follow-up<sup>a</sup></b>			
Major	1.000	–	
None	2.181	0.907 to 5.242	0.081
Minor	0.885	0.270 to 2.889	0.840
Previous OAT complication <sup>a</sup>	0.630	0.352 to 1.126	0.119
EQ-5D visual scale	1.017	1.001 to 1.034	0.032
<b>Participants with antiphospholipid syndrome excluded (n = 245)</b>			
Age, years <sup>a</sup>	1.025	1.003 to 1.049	0.027
Male <sup>a</sup>	1.303	0.736 to 2.306	0.364
Duration of self-monitoring, months <sup>a</sup>	1.003	0.997 to 1.010	0.295
<b>Procedure during follow-up<sup>a</sup></b>			
Major	1.000	–	
None	2.023	0.836 to 4.893	0.118
Minor	0.734	0.221 to 2.443	0.614
Previous OAT complication <sup>a</sup>	0.752	0.412 to 1.374	0.354
EQ-5D visual scale	1.019	1.003 to 1.036	0.020
Target INR	0.480	0.246 to 0.939	0.032

<sup>a</sup>Variables the model was required to include. INR = international normalised ratio. OAT = oral anticoagulation therapy.

Ward et al; BJCP 2015



# Point-of-care versus central laboratory testing of INR in acute stroke



Zenlander et al; Acta Neurol 2017

## Conclusioni

- Ottima efficacia e sicurezza dei POC nei pazienti in AVK
- Effetto mediato dal miglioramento del TTR?
- Necessaria selezione del paziente (e del medico?)
- Carico dei costi



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