Adherence to VKA treatments : What are the needs?

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Conflict of interest

No conflict of interest

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The issue of adherence

- According to NICE, between a third and a half of all medicines prescribed for long-term conditions are not taken as recommended[1]
- Poor adherence can severely compromise the effectiveness of treatment[2]
- Poor adherence not only affects clinical outcomes, but also represents a waste of healthcare resources[2]

1. Nunes V et al. (2009). Clinical Guidelines and Evidence Review for Medicines Adherence: involving patients in decisions about prescribed medicines and supporting adherence. London: National Collaborating Centre for Primary Care and Royal College of General Practitioners.

2. World Health Organization. Adherence to long-term therapies: evidence for action (2003)

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The VKA : Why a great adherence is specifically needed?

- Several million of patients are treated with VKA in Europe (elderly++)
- VKA is one of the drug classes leading to highest rates of emergency admissions [1]
- In France, hospitalization related to drug adverse events are mainly due to VKA exposure [2].
- For patients with atrial fibrillation receiving VKA, the overall median incidence of major bleeding was around 2 per 100 patient-years [3]

1. Budnitz et al., NEJM 2011
2. Les anticoagulants en France en 2012 : état des lieux et surveillance ; ANSM ; juillet 2012
3. Roskell et al., Europace 2013

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Adherence improvement ⇔patients interview

The research proved that patients stayed within their allocated INR range for a greater degree of time when they self-managed their own anticoagulant[1,2].

Therapeutic education : the best approach

- **Time consuming**
- **Needs a specific formation**
- **Multidisciplinary team**

VKA counselling : a realistic option

=>Offers to the patient information and tools for an adapted use of VKA treatment :

- Detection of side effects
- INR monitoring : why it is important, how to read it
- Why it is important to have a VKA card always with me…

1. Leger et al., J. Mal. Vasc 2004
2. Brunie et al., Educ Ther Patient 2011

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How to perform a VKA counselling ?

Professional knowledge	**Mechanism of action** **(self)monitoring** **detection of signs of overdosage or ineficiency** **therapeutic interactions** **food interactions…**
Know-How	**Deliver key messages** **Prioritize informations as necessary** **Make repeat/rephrase** **Obtain informations (open questions..)…**
Social-skills	**Present yourself** **Be empathic** **Manage the non verbal communication**

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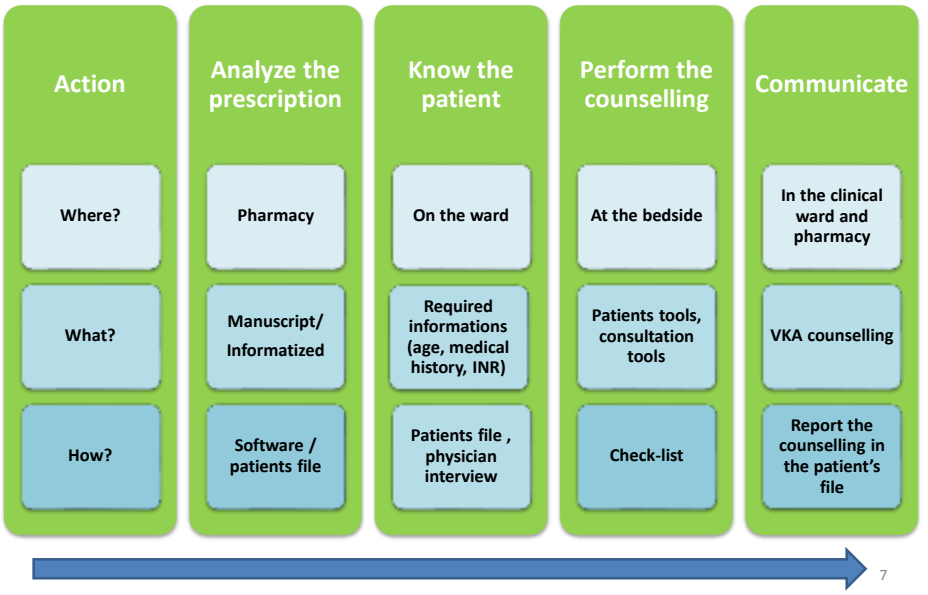
VKA counselling alone is not enough



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Let's Go!

- Ms. B, 72 years old (Size : 158 cm; Weight : 48 Kg), was diagnosed an atrial fibrillation (AF) during a check up due to an increasing tiredness. She is suffering from hypertension since 10 years, which is treated with enalapril 20 mg once a day and takes ibuprofen in case of articular pain or headache. During her check up, a renal impairment (cl creat : 60 ml/min MDRD) due to her age was also found.
- Ms. B lost her husband 4 years ago but her daughter lives not far and she uses to see her mother every Sunday. Ms. B daily practices gardening and is proud to formulate that her food essentially comes from her garden.
- Ms. B was prescribed warfarin, 2 mg every evening

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1)What arguments led to initiate anticoagulation?

Congestive heart failure/ LV dysfunction	1
Hypertension	1
Age ≥ 75	2
Diabetes mellitus	1
Stroke/TIA/TE	2
Vascular disease (CAD, CArD, PAD)	1
Age 65-74	1
Sex category (female)	1

Ms. B:

- **72 years old**
- **Female**
- **Hypertension**

=

3

YES

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2) What is the target INR ? 2-3

Rq: There are currently available lightweight portable instruments to facilitate prothrombin time measurement (expressed as INR) using a drop of capillary blood :

- The CoaguChek S from Roche Diagnostics

- The Hemosense INRatio from Sysmex / Alere

3) Does a dosage adaptation due to her renal insufficiency needs to be performed?

Hepatic metabolisation
Renal elimination of the inactive metabolite

NO : Adaptation is only based on INR

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4) According to you, what kind of skills does Ms B need to acquire ?

Generally	*Specifically*
• Understand why her treatment was initiated and what are the potential complications without this treatment • Understand the need of monitoring INR • Know the target INR • To detect signs of hemorrhage or thrombosis (her daughter) • Know what to do in case of oversight • Inform all health professionals about her anticoagulant treatment	• Interaction with NSAIDs (ibuprofen) • Interaction with food (gardening)

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4) What should you do to make sure that Ms. B understood your key messages?

Ask to Rephrase /repeat

Ask open questions..

Play scenario…

Three years later, Ms. B needs to undergo an operation for a hip replacement.

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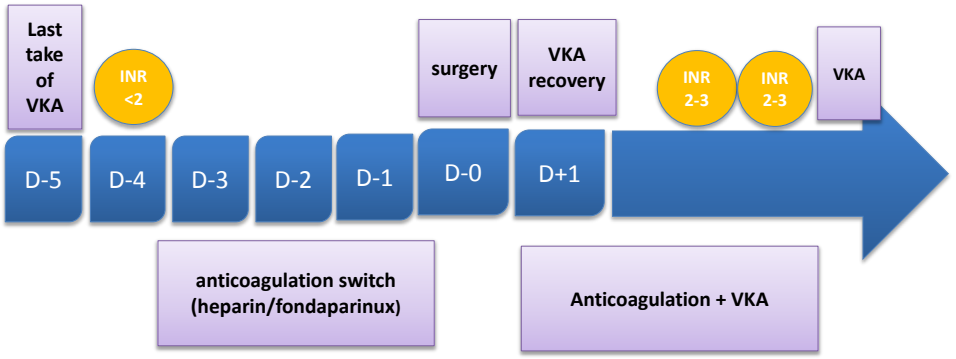
4) What are your recommendations regarding anticoagulation around the surgery?



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Situation number 2

- Mr. T, 32 years old (Size : 175 cm; Weight : 72 Kg), lives in London and was diagnosed a prolapsed mitral valve. He had mechanical mitral valve replacement surgery in September 2000 and warfarin 5 mg was prescribed. Unfortunately, INR is fluctuating despite a good adherence.

- Mr. T doesn't take any medication. Mr. T is married, has three kids and uses to travel a lot for his job for the past 6 months (around 4 back and forth per month to Shanghai and New-york).

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1) Is it possible to switch for a NACO?

- No novel anticoagulant is indicated in mechanical valve replacement.
- In the phase II RE-ALIGN study comparing dabigatran *vs* warfarin with patients who have mechanical heart valves assessing safety use, dabigatran was associated with increased rates of thromboembolic and bleeding complications, as compared with warfarin,

=> no benefit and an excess risk.

Eikelboom JW, NEJM 2013.

- Check if Mr. T takes his treatment as recommended

2) What is the target INR in this indication ?

3-4

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How is calculated the target INR in mechanical valve replacement?

Target INR depends on kind of prothesis, its location and inherent patient's risks

Thrombogenic power of prothesis	Risks related to the patient	
	No risk	≥ 1 risk factor
weak	2-3 (2.5)	2.5-3.5 (3)
moderate	2.5-3.5 (3)	3-4 (3.5)
high	3-4 (3.5)	3.5-4.5 (4)

Inherent patient's risks and prothesis location:

- history of thromboembolism, AF
- EF < 35 %
- mitral or tricuspid location
- mitral stenosis

ESC, 2012

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4) According to you, what kind of skills does Ms. B need?

Generally	*Specifically*
• Understand why her treatment was initiated and what are the potential complications without this treatment • Understand the need of monitoring INR • Know the target INR • Know what to do in case of oversight • To detect signs of hemorrhage or thrombosis • Inform all health professionals about his anticoagulant treatment • Interaction with NSAIDs (ibuprofen) • Interaction with food (gardening)	• Manage his treatment with jet lag • Anticipate potential loss of suitcase

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VKA and travels..

Manage his treatment with jet lag

- The better is keeping same schedules.
- It would be recommended to use mobile phone monitoring based on usual schedules to anyone who travels a lot

Anticipate potential loss of suitcase

- Keep medications in your handbag. Keep your prescription with you

In case of self monitoring : Few points to bear in mind if you are travelling

- Be sure to carry a letter from your doctor explaining what the monitoring machine and strips are needed for.
- Be sure to have some sort of cool-bag with you to keep your test strips cool.
- Be sure to have enough strips. You might find that, being abroad, your INR might fluctuate more than usual. New foods and dehydration can affect your INR. Drink plenty of (bottled) water.
- Have confidence in your own ability to self-test. Remember that nobody knows your body better than you do!

http://www.anticoagulationeurope.org/experiences/yvonnes-experience-of-self-monitoring

Barts Health NHS
NHS Trust

Rivaroxaban patient counselling checklist

- **Indication for anticoagulation**
  - Explanation of AF, risk of stroke
- **Name of drug**
  - Rivaroxaban (Xarelto® is trade name)
- **Give rivaroxaban information leaflet**
- **Action of rivaroxaban**
  - Makes blood less sticky, takes longer to clot
- **Difference with warfarin (if applicable)**
  - No INR monitoring; unable to monitor anticoagulant effect
  - Same dose to be taken once each day
- **Dosing**
  - Take specified dose once each day
  - Swallow whole with water, do not open capsule
  - Must be taken with food
  - Same time every day
  - Action on missed dose: take as soon as you remember, within 12 hours, do not double up
- **Importance of concordance**
  - Unable to monitor anticoagulant effect
  - Implications of poor concordance: increased risk of stroke
  - Implications of overdose: increased risk of bleed
  - If problems with remembering to take, discuss with GP

- **Bleeding/Unexplained bruising**
  - Mild, self-terminating episodes to be expected due to nature of medicine (similar to warfarin)
  - Regular or excessive ongoing bleeding go to A&E, inform of symptoms and that rivaroxaban being taken
- **Other side effects**
  - Likely to experience dizziness, weakness and gastro upset
  - Report side effects to MHRA via Yellow card/website
- **Concomitant Medicines**
  - Avoid long-term use of NSAIDs
  - Check with GP/pharmacist before starting any new medicines
- **Alert card**
  - Keep with you at all times e.g. in wallet
  - Show to healthcare professionals
- **Pregnancy and Breastfeeding**
  - Avoid
- **Contact Sports (e.g. boxing, rugby, football)**
  - Avoid (risk of internal bleeding)
- **Inform all healthcare professionals**
  - Inform hospital doctors, pharmacists, dentists etc. prior to any treatment
  - Surgical interventions can increase risk of bleeding, request GP to seek specialist advice
- **Repeat Prescriptions, Follow up appointments**
  - Initiated in hospital, will be given full supply for trial purposes
  - Ensure do not run out of medicine

Signature of Patient (or representative or advocate)..... date.....

Patient or advocate name.....

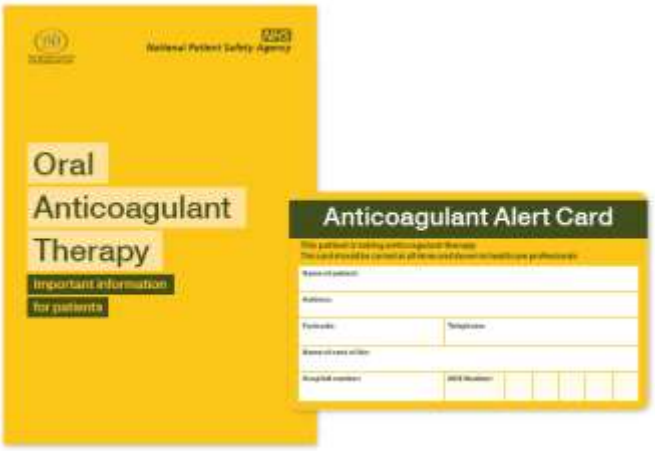
Signature of BLT practitioner:.....date.....

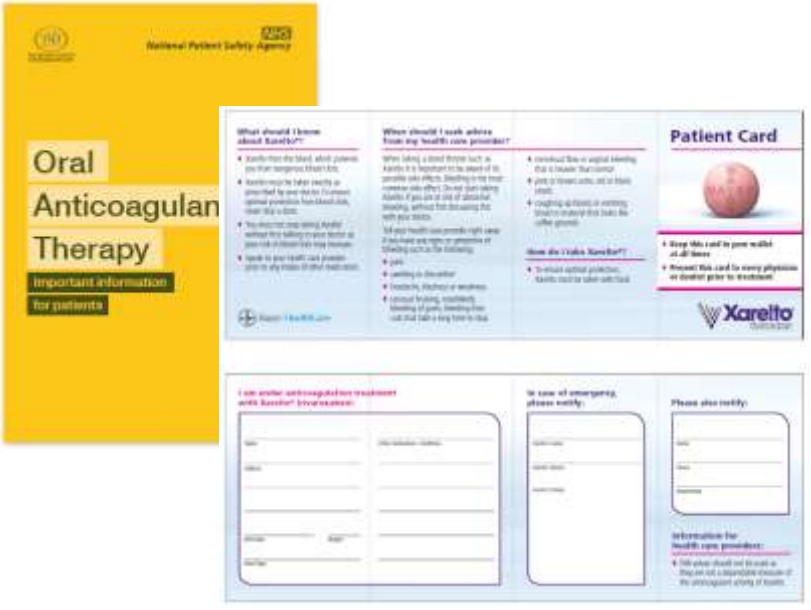
Name of practitioner and designation.....

- How would the counselling differ if prescribed dabigatran?

Counselling

- Reduces the chance of unwanted blood clots forming which helps prevent strokes
- Take regularly ,
  - any time is ok – when would be easiest for you
  - Warfarin – evening to coincide with INR test
  - Forgotten doses
    - W – if before midnight
    - D – if within 6 hrs of next dose (miss)
    - R/A – take immediately, do not double within the same day
- Like all medicines – unwanted side effects
  - If unusual bleeding, such as dark or bloody stools, urine or unexplained bruising tell your doctors
  - NSAIDs can't be taken with anticoagulants
  - Specifics Dabigatran – Indigestion


National Patient Safety Agency
Oral
Anticoagulant
Therapy
Important information
for patients
Anticoagulant Alert Card


National Patient Safety Agency
Oral
Anticoagulan
Therapy
Important information
for patients
Patient Card
Xarelto


Oral
Anticoagulan
Therapy
Important information
for patients
National Patient Safety Agency
PATIENT
ALERT CARD
Xarelto® 15mg
Xarelto® 20mg
• KEEP THIS CARD WITH YOU AT ALL TIMES
• PRESENT THIS CARD TO EVERY PHYSICIAN OR DENTIST PRIOR TO TREATMENT
Patient Card
Xarelto


Oral
Anticoagulan
Therapy
Important information
for patients
National Patient Safety Agency
PRADAXA®
PATIENT ALERT CARD
Patient Card
Xarelto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Therapy
Important information
for patients
National Patient Safety Agency
Patient Card
PATIENT
ALE
Xarelto
Xarelto
Eliquis®
(apixaban)
Patient
Alert Card
5 mg and 2.5 mg twice daily

Important patient instructions

Take your drug exactly as prescribed (once or twice daily).
No drug is no protection!

Never stop your medicine without consulting your physician.

Never add any other medication without consulting your physician, not even short-term painkillers that you can get without prescription.

Alert your dentist, surgeon or other physician before an intervention.

Concomitant medication

Name:	Dose:

Emergency information

Standard tests do no quantitatively reflect level of anticoagulation!

Name & telephone of patient relative to contact if emergency:

Patient blood group (+ physician signature):

Atrial Fibrillation
Oral Anticoagulation Card

for non-vitamin-K anticoagulants

Patient name: DOB:

Patient address:

Oral anticoagulant, dosing, timing, with or without food:

Treatment indication:

Treatment started:

Name and address of anticoagulant prescriber:

Telephone number of prescriber or clinic:

More info:
www.NOACforAF.eu
www.noacforaf.eu

Planned or unplanned visits

Date (or date range):	Site (GP; clinic; cardiologist; ...):	To do / findings:

Recommended follow-up

(see EHRA at www.NOACforAF.eu for information & practical advice)

Check each visit:
1. Compliance (pt. should bring remaining meds)?
2. Thrombo-embolic events?
3. Bleeding events?
4. Other side effects?
5. Co-medications and over-the-counter drugs.

Blood sampling:
- monitoring of anticoagulation level is not required!
- yearly: Hb, renal and liver function
- if CrCl 30-60 ml/min, >75y, or fragile:
  6-monthly renal function
- if CrCl 15-30 ml/min:
  3-monthly renal function
- if intercurring condition that may have impact:
  renal and/or liver function

Date	Serum creatinine	Creatinine clearance	Hemo-globin	Liver tests

In conclusion

Patients interview

⇔

Adherence improvement

⇔

improve benefit-risks ratio

- Professional knowledge is necessary but not enough to perform a relevant VKA counselling
- You have to know your patient and start based on him
- You need to adopt the right attitude to get over messages
- Be empathic
- Make sure that your patient understood key informations

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Thank you for your attention

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