Pre-Donation Interview by Nurses (PDIN)

Experimenting PDIN at EFS

Dr D. Benomar, Director Blood Collection, Paris
EFS (Etablissement Français du Sang)
The French National Blood Service

EFS = STRUCTURES
- 17 regional facilities
- 150 donation fixed sites
- 40 000 mobile blood drives

EFS = SKILLED AND SPECIALIZED STAFF
- 9 810 Employees
- 629 Physicians
- 1 285 nurses. Among them 896 with more than 3 years of seniority

MOTIVATED DONORS
- 1 625 735 donors
- 347 530 new donors
- 3 130 016 applications for donation
- 2 833 351 blood donations (whole blood, plasma et platelets)
PDIN Project Team

- **Sponsor**: Donor Relationship Manager
- **Project Manager**: HR Director of EFS
- **Pilot**: Directorate General for Medicine, security, quality and risks (in French DGD MSQR)
- **Regional references**
  - **Donation**: Manager of the transfusion chain
  - **HR Director**: EFS in IDF (Paris Region)
PDIN - SUMMARY

1. PDIN Goals and Context
2. Draft Legislation about PDIN
3. Overall scope and sizing
4. Medical issues
5. HR issues
6. Legal issues
7. Project communication
8. Evaluation
9. Project stages
PDIN- GOALS and CONTEXT

Goals

- Respond to the shortage of physicians
- Allow nurses to learn new skills and diversify their activity
- Allow the physicians to valuate their medical expertise and their managerial skills
- Set up a national sustainable project guaranteeing self-sufficiency with a preserved level of security
- Maintain the level of efficiency

Show that EFS is able to implement the pre-donation interview by nurses in an organized and sustainable manner. Capitalizing on the medical and technical skills of the staff to maintain the high level of security for all the donations.
Experimenting in France (as is done in many countries) a non-medical pre-donation interview with the possible use of a physician if needed.

Following a first experimentation in 2006-2007 organized in three pilot regions (Bourgogne Franche-Comté, Centre-Atlantique and Pays-de-la-Loire) which demonstrated that trained and qualified nurses are able to perform pre-donation interviews in a rigorous and standardized method with excellent reliability.

Legal vector: a draft of the blood II decree which forecasts the testing of the PDIN for 2 years

PDIN: an innovative, structuring project that meets the objectives of the future EFS.
1st Experimentation in 2006 – 2007

- **Main goal**: feasibility and effectiveness of a PDI conducted by a trained nurse.

- **Type of study**: Study in 2 stages during a year between October 2006 and October 2007 with the collaboration of a biostatistician.

- **Scope**: 3 sites, mobile blood drives only.

- **Professionals involved**: 2 physicians + 2 nurses for each site, volunteers and working in pairs (one physician with one nurse).

- **Training**: 5 days of a theoretical training for the 12 participants + a minimum of 15 days of a practical training for the 6 nurses.

- **Target Population**: consenting donors.

- **Execution**: the donors received successively by the physician and the nurse in random order determined by drawing lots.
Stage 1 — Methodology

- Donor candidates have been received successively by the doctor and the nurse in an order defined by random draw
- The donor was advised of the finale decision by the doctor after having look of both decisions
- An analysis after collection allowed a daily management of the encountered difficulties

Stage 1 — Results

- 1940 donors were received, including 253 new donors (13%)
- In 1921 cases (99% of total), nurses were able to take a decision without the doctor’s advice
- The concordance rate decisions taken by doctors and nurses is 96.4%
- In 38 cases (1.9%), the nurse rejected the donation and the doctor accepted the candidate
- In 31 cases (1.6%), the doctor rejected the donation and the nurse accepted the candidate
- Precautionary principle : 1 case
- Interpretation of a symptom : 13 cases
- Failure in the interview : 7 cases
- Failure in the medical review : 4 cases
- No identification of a cause for adjournment : 6 cases
STAGE 1 — Conclusion

Great quality of involvement of all stakeholders in the study.

Good acceptance from donors and associations.

Good acceptance from EFS teams.

Excellent consistency of physicians and nurses decisions.

The few mismatches analyzed (31 versus 38) showed that the nurse doesn’t generate additional risk and doesn’t decrease the security level reached with an interview conducted by a physician.
Stage 2 - Methodology

- The donor has been received either by the physician following the usual procedure or by the nurse according to new defined and formalized method.

- The objective of this phase was to compare the rejection rate and frequency of the contraindications between the doctors and the nurses and to show the equivalence of the decisions made by the doctors and the nurses to adjourn blood donation candidates.

Stage 2 — Results

- The six nurses received 3222 donors, which means 537 donor per nurse.

- During the same period and the same scope, 52 doctors received an average of 403 donors (Total = 20,956 donors).
Stage 2 – Conclusion

- The average and median rejection rates are slightly higher among nurses than among doctors.
  - The average rejection rates are 12.5% for nurses against 12.2% for physicians.
  - The median rejection rates are 12.1% for nurses against 10.0% for physicians.

- If donors are generally contraindicated in the same way: donor risk (22.2 versus 25.6), receiver risk (75.9 versus 74.4), the lack of knowledge leads the nurses to ventilate these contraindications in different families.

- The study does not show if these results are due to the interlocutor (nurse vs physician) or if it is a consequence of the nurses inexperience while doctors practice these interviews for years.
Final Conclusion

Skilled nurses are able to conduct the pre-donation interviews in a rigorous and standardized method with excellent reliability.

Conclusions of the qualitative analysis

The experiment shows a change in the professional positions and the relationships between all the actors without generating major difficulties.

The pairs (physician-nurse) had a key role in the implementation of the experimentation. Motivated and valued by the experience, the nurses were quickly autonomous conducting the interviews. Donors and associations representing them have willingly participated in this new evolution not disturbing from their point of view.

All the teams, except one team, accepted without any reluctance the professional positions changes - the nurses passing from practicing the donation to conducting the interview.

Finally, the experimentation emphasized that the physicians, without an openly expressed opposition to the experimentation, still feel challenged in their identity because of the new role given to the nurses in the donors selection.
Conclusion of the study: The key factors of the success

- A precise control involving national and regional officials and some experts.

- The volunteering of the nurses.

- The strong investment on the team members who conduct the experimentation (doctors, nurses and secretaries).
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The law:

Decree discussed by the Social Section of the State Council April 8, 2014

Pre-donation interview by a state graduated nurse:

- Derogatory plan for 2 years.
- Target = trained state graduated nurse, seniority > 3 years in the practice of donation.
- Attendance of a physician (1st donation, risks which requires a physician, when the cause of the contraindication is misunderstood by the donor or whenever the donor requests it).
- Assessment after 18 months regarding evaluation reports (EFS, Army Blood Transfusion Center). No report from the French Health Authority is needed.
- Implementation of the decree six months after its publication.
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Overall scope and sizing:

- **Geographical perimeter:**
  - Experiments conducted in all regional institutions, including overseas regions, and in each region on one or multiple sites.

- **Functional perimeter:**
  - In mobile blood drives (rural, urban and enterprise) and some fixed sites or blood donation houses (estimated of 250,000 PDIN for about 16 months).
  - Donation Types affected by the experiment: whole blood and apheresis.
  - One hundred nurses in experimentation in respect of the employment rules.
  - Regional steering by a pair HR / Responsible of Collection and identification of a regional referent for assessment.

PDIN is a strategic and unifying project that mobilizes all the skills of the institution. It is what makes it complex.
Overall scope and sizing for Paris Region

- **Targeted geographical perimeter:**
  - All mobile blood drives and the 4 major Parisian fixed sites (Trinité, Cabanel, Crozatier et St Louis)

- **Targeted functional perimeter:**
  - 11 to 12 nurses

- **Estimated PDIN volume for 12 months**
  - 17,975 PDIN whole blood in mobile blood collection
  - 6,000 PDIN in fixed sites, shared between whole blood and apheresis donations
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A new document listing all the contraindications

A more detailed document than the former one specifying precisely all the blood donation contraindications. It guarantee a better harmonization of the answers given to donors.

- It used by doctors and nurses: the pathologies needing a medical advice will be listed.
- It can be put online and accessible to donors.
- No additional questions to the official survey.
- The survey lists all the pre-donation questions. It can serve as a guide.
- Donor responses analysis will be done thanks to the new document. Physician advice can be requested by the nurse if she has a doubt.
Apheresis donation

There is no medical or epidemiological argument in favor of an in-depth medical examination before an apheresis donation:

- Selection criteria and regulated collection volumes are formalized in the national EFS documentation.

- In order to respond to the staff apprehension regarding the specificity of this act, addendums to the decree are proposed:
  - PDI for a 1st apheresis donation has to be done by a physician.
  - PDIN for an apheresis donation has to be done by an apheresis-authorized nurse who did at least 100 whole blood PDIs.
traceability of the intervention of doctors

Système de traçabilité des interventions des médecins proposé sous Inlog

- L'IDE autorise le don
  - L'IDE a réalisé l'ensemble de son questionnaire
  - L'IDE autorise le donneur
  - L'IDE ajoute le donneur et renseigne la CI

- Prérèquis : l'IDE doit aller au bout du questionnaire avant de faire appel au médecin
  - Pour éviter une autorisation par le médecin puis une CI par l'IDE sur un autre sujet
  - Pour éviter plusieurs interventions du médecin

- L'IDE a besoin du médecin
  - L'IDE pose un examen « médecin »
  - Intervention du médecin

- Le médecin autorise le don
  - L'IDE met OK en résultat de l'examen médecin
  - L'IDE autorise le donneur
  - Le médecin ajoute le donneur
    - L'IDE met refusé en résultat de l'examen médecin
    - L'IDE ajoute le donneur et renseigne la CI

Légende :
- Action
- Impact dans Inlog
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The doctors

- Physicians trainers for the nurses are designated among the volunteers that currently trains the new doctors.

- A doctor conducts interviews of primo-donors and first Apheresis donations.

- In a fixed site, the doctor is available at any time (emergency, response to nurses questions, contraindications...).

- A specific job description for PDIN practitioners is created.

- A dedicated communication is created (physicians' leaflet).
The nurses

- Experimentation with volunteers nurses.

- Criteria to select the nurses:
  - Having at least 3 years of seniority collecting blood at EFS.
  - Having at least a 24 hours/week job (minimum to be allowed to collect blood).
  - Ability to collaborate trustfully and to report regularly to physicians.
  - Real sense of responsibility and autonomy (good knowledge of self-limits).
  - Communication skills: listening and speaking.
  - Being calm, quiet and rigorous.
  - Privacy ++++, punctuality, availability, involvement and investment, ability to use medico-technical Software.
  - Motivation.

- Training and certification.
The nurses

- **Half-day planning** for either collecting or PDI.
- Recognition during the experimentation by a financial bonus.
- To be eligible for the apheresis PDIN, a nurse shall practice or have practiced the collection by apheresis.
- A specific job description in PDIN project.
- A dedicated communication (leaflet).

PDIN has to preserve the heart of nurses’ job: blood collection
The training of nurses

Skills acquisition, certifications – A common theme: The interview survey.

Prerequisites:
- 3 years of seniority.
- Good knowledge of the transfusion chain.
- Certificate of Training in Emergency First-Aid.

Trainings:
- Practical training in parallel with theoretical training.
- About 40 hours: tutored training (one tutor and few trainer physicians) on the medico-technical software and the pre-donation interview.
- Certification on the analysis of professional practices.

EFS national process to manage the nurses certifications.
The training of nurses

Theoretical training

National 35 hours training + Assessment:

- Training documents are national framework documents.
- Comprehension of the nurse’s role in the pre-donation interview.
- Mastering the environment of the pre-donation interview: regulation, software, transfusion chain, the orientation of the donor, the types of donations, blood safety, traceability and quality, donor and recipient risks.
- Practicing the pre-donation interview.

Practical training

- The training can be done on any type of collection (fixed and mobile, whole blood and apheresis). Nurses may assist to the interviews of primo-donors made by doctors with the agreement of the donor.
- About 100 interviews
The training of nurses

**Training rhythm**
- The hundred nurses should be trained no later than three months after the start of the experimentation.
- 3 groups of 12 nurses are trained at a national level to be ready the first day the experimentation.
- 6 months after the publication of the decree, the other nurses should be trained in all the regions.

**Following the trainings when the objective of 100 nurses trained is achieved**

Regular trainings to enroll, in PDIN program, new volunteer nurses who have achieved their 3 years of experience.
## Theoretical content (1/2)

Active teaching method (many role playing games / simulation exercises)

<table>
<thead>
<tr>
<th>Theme</th>
<th>Details</th>
<th>Duration in hours</th>
</tr>
</thead>
</table>
| Introduction                         | Welcome  
Roundtable  
Presentation of EFS (role, organization ...)  
Review of various European cases  
PDIN project planning  
Results of 2006 experimentation  
training organization | 3 |
| Role of the nurse In the PDI        | Legal context: Blood decree  
Why a PDI, which risks are we trying to avoid? (introduction to infectious diseases ...)  
Description of job roles : Nurse and Doctor  
HR aspects: impact on the job of the state graduated nurses  
Best practices (reminder of the statutory texts and laws)  
Document management  
Quality assurance  
Privacy | 4 |
| Pre-donation Interview               | Presentation of the survey (which risk behind each question: risk for recipient / donor / both)  
donor risk and recipient risk: document referencing medical contraindications (focus on apheresis),  
haemovigilance  
Presentation of the detailed (commented) version of the survey  
Arguments for the rejection causes which do not require medical advices (such as hypertension)  
Post-donation information (keywords) | 14 |
| Donation orientation (qualitative eligibility) | Promotion of donation act, donor orientation (good practices), loyalty | 3 |
### Theoretical content (2/2)

<table>
<thead>
<tr>
<th>Theme</th>
<th>Details</th>
<th>Duration in hours</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Behavior skills</strong></td>
<td>Preparing the new relationship with the donor:</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Welcome of the donor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Knowing how to explain the experimentation to donors (role of the nurse, role of the doctor)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Explain the rejection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Conflict management</td>
<td></td>
</tr>
<tr>
<td></td>
<td>==&gt; exercise with sub-groups with result presentation/debrief and synthesis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Communication within the team and with external partners</td>
<td></td>
</tr>
<tr>
<td><strong>Medico-Technical Software</strong></td>
<td>Medico-technical software « Philosophy »</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>What is it:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- a collection ?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- an exam ?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- ...</td>
<td></td>
</tr>
<tr>
<td></td>
<td>traceability</td>
<td></td>
</tr>
<tr>
<td></td>
<td>data quality, responsibility for input the correct to data ...</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Initiation to the medico-technical software (navigation, items ...)</td>
<td></td>
</tr>
<tr>
<td><strong>Round table</strong></td>
<td>Regarding to the questions asked at the beginning of the training, time should be allocated to exchange with the Legal Direction and the HR Direction (1st experimentation stage)</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total for the theoretical training (by group, on site)</strong></td>
<td></td>
<td>35</td>
</tr>
<tr>
<td><strong>Evaluation + CERTIFICATION</strong></td>
<td>Knowledge test:</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>- pre-training (baseline to measure the impact of the training)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- At the end of the training</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- A couple of weeks after the training</td>
<td></td>
</tr>
<tr>
<td><strong>Observation (before the practical training)</strong></td>
<td></td>
<td>7</td>
</tr>
<tr>
<td><strong>Practical training</strong></td>
<td>5 to 10 PDI /100 interviews</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>+ practical training to the software usage + data input during pre-donation interviews + control by a doctor</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>76</td>
</tr>
</tbody>
</table>
PDIN – HR ISSUES: Training of the nurses

Organization of the nurses training

<table>
<thead>
<tr>
<th>After Application</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4 and 5</th>
<th>Week 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge Test</td>
<td>3 days of theoretical training on site</td>
<td>Observation in the field (attend to PDI without intervention - allows to understand the job and help to ask questions in week 3)</td>
<td>2 days of practical training on site + Knowledge Test</td>
<td>Practical training</td>
<td>First Exam + Certifications</td>
</tr>
<tr>
<td>Allows to have a baseline to measure the impact of the training</td>
<td>21h</td>
<td>7h</td>
<td>14h</td>
<td>42h</td>
<td>1h</td>
</tr>
</tbody>
</table>

Total: 76 hours (35 hours of theory + tutoring by doctors)
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Responsibility

The scope of tasks done by the practitioners changes. It has the following consequences in terms of responsibility:

**For a nurse**: responsibility is the same as the doctor performing the same task. An error engages the financial liability of the EFS, except if the error is not related to the service and then engages the personal responsibility of the nurse. The nurse engages his personal criminal liability for fulfillment of an offense.

**For a physician**: The responsibility is neither aggravated nor enhanced by PDIN and she/he is not personally responsible for possible errors committed by the nurse.
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# PROJECT COMMUNICATION – INTERNAL ARRANGEMENT

<table>
<thead>
<tr>
<th>TARGET</th>
<th>MESSAGE</th>
<th>TOOL</th>
</tr>
</thead>
</table>
| All the employees | Presentation of the project: background, objectives, scope (collections, donations and staff concerned, duration) Establishment of an internal application process for volunteer nurses who would like to join | - Communication about the project via EFS MAG and EFS NEWS  
- News on the Intranet  
- **FAQ in employees space and the collections space**. Prints can be offered locally |
| EFS employees (nurses and doctors) not concerned by the project | Impacts on the organization of collections during the training of the nurses, Experimentation plans communication tools | - Local meetings using a unique support (PowerPoint document) |
| Eligible doctors and nurses in the experimentation | General announcement of the project before the selection stage | - Poster  
- Document for the nurses (leaflet) |
| Management: Directors, collection chiefs and communication officers, HRs, | Presentation of the project: the protocol, the process of internal selection, job descriptions, training, planning and communication tools | - Usual planned meetings  
- Presentation of the unique PowerPoint document  
- Project file: the protocol, the process of internal selection, job descriptions, training and planning |
<p>| Management not concerned by the project | Presentation of the project: background, objectives, scope and project progress | - The unique PowerPoint support is made available to directors for local communication |</p>
<table>
<thead>
<tr>
<th>Target</th>
<th>Message</th>
<th>Tool</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federation of Voluntary Blood Donors</td>
<td>Presentation of the project</td>
<td>• Official communication</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• PowerPoint document</td>
</tr>
<tr>
<td>Associations and collection correspondents</td>
<td>Presentation of the project</td>
<td>• PowerPoint de présentation, diffusé via les Directeurs de communication régionaux</td>
</tr>
<tr>
<td>Donors</td>
<td></td>
<td>• Poster on collection sites</td>
</tr>
</tbody>
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Evaluation

- Pilot of the evaluation: DGD MSQR (French institution: Directorate General for Medicine, security, quality and risks).

- The proposed lines of evaluation:
  - The organization and execution of the experimentation:
    - Ability of EFS to manage the whole project
    - Relevance of the training system
    - Qualitative analysis of the relationship between doctors and nurses
  - Security (Haemovigilance in the heart of the project)
  - Economical impacts

- Creation of an evaluation committee comprising people from different institutions (EFS, Directorate General for Health, Army Blood Transfusion Centre, National Health Products Safety Agency and High Health Authority).

- A repository (metrics and targets) and infrastructure (collection and analysis of data) to complete the assessment will be presented to the authorities.
Evaluation

- An external provided will be assigned to monitor the project.
- Assessment referents have to be identified in the different regions, to transfer non-automated information that will feed the evaluation.

In accordance with the PDIN project objectives, evaluation stages will allow to validate, develop and/or readjust some points with relevant metrics and to prepare the assessment report to the authority.
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Prochaines étapes

Parution du décret

Mai
- Mail aux Directeurs
- Choix des sites & nb IDE

Juin
- Dialogue OCE (15/05)
- Consultation sur décret Bang (19/05)
- Information CF
- Communication du planning de formation

Juillet
- Kit de formation IDE
- Choix des dates de formation
- Communication du dispositif d’éval.

Août
- Rédaction leaflet médicale
- Finalisation et maquette des leaflets IDE et médicins
- Distribution des leaflets IDE et médecins

Septembre
- Redac FAQ
- Finalisation du référentiel
- Appel d’offre
- Choix prestataires

Octobre
- Cadrage du dispositif d’éval.
- Racette
- Information des référents régionaux

Novembre
- Début de l’évaluation

Décembre
- Recommandation dans certaines régions
- Lancement des EPDI

Janvier
- Retard potentiel dans certaines régions

27 juin
Execution of the experimentation

A fairly rapid scalability in the experimentation which allowed to achieve 7.3% PDIN of all pre donations interviews.

More PDIN in mobile blood drives, less PDIN for apheresis donation
Nurses gained efficiency and confidence very quickly

Security

Need of a doctor help particularly low : 4,5%
Good relationship between doctors and nurses
Nurses reject more candidate donors than doctors : 10,54% VS 9,24%
Similar practices between nurses and physicians regarding the complementary tests : 4,12 VS 4,26
No observable difference on the positive markers HIV / HBV / HCV / HTLV-1 / Syphilis
No difference between PDI by nurses and PDI by doctors regarding side effects
Efficiency

2.3 % of nurses were selected to do PDIs

At this level, it is difficult to evaluate the efficiency of the nurses:

- PDI by nurses per hour:
  - 2.58 in March/April
  - 3.39 in May
  - 3.76 in June

- PDI by doctors per hour: 7.7

... The nurses are learning ...

... Convergence with doctors is progressive...
Objective of PDIN project in Paris region

25 200 PDIN per year

- 80 mobile blood drives per year and per nurse with an average of 30 PDIN.

- 100 days on fixed sites with 20 PDIN per day and per nurse. 50 % whole blood and 50 % Apheresis.

Target : 7.3 % of all the pré-donations interviews.
MONTHLY PROGRESS OF PDIN at a NATIONAL LEVEL

The target is achieved thanks to some people working in compliance with the objective.

The result is good globally but not individually.
THANK YOU