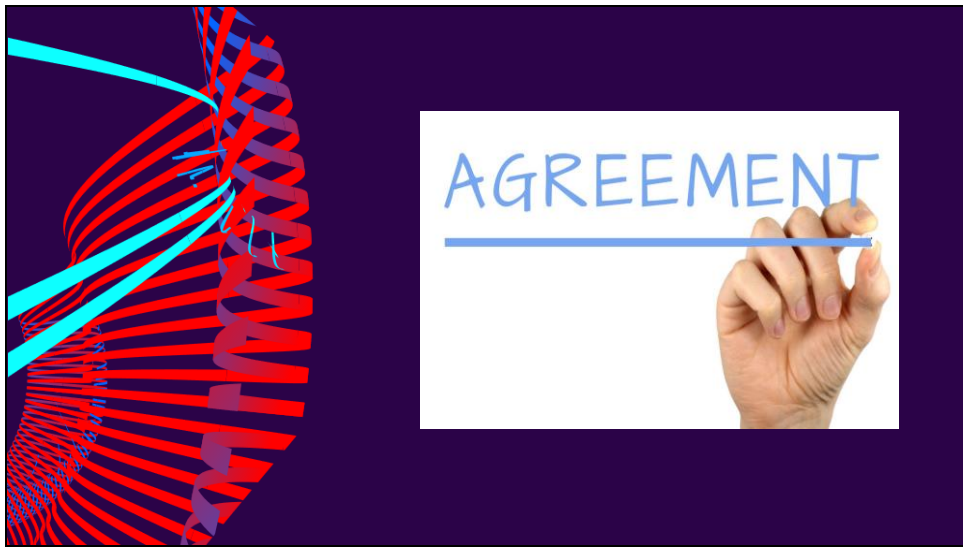

Summary



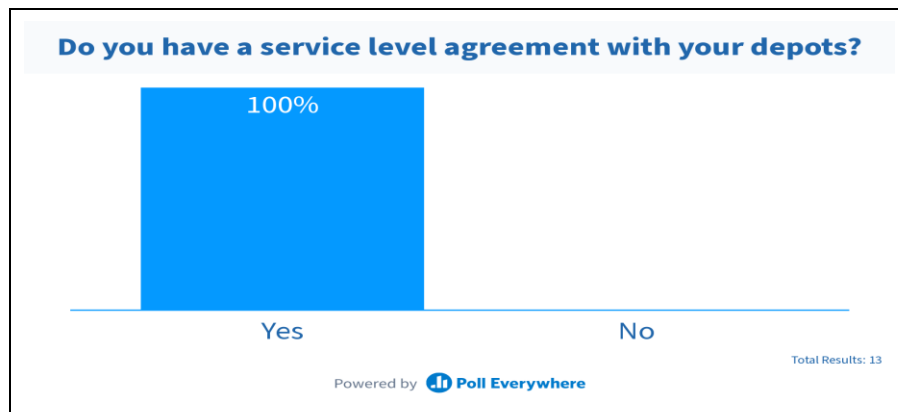
01/06/2023, Erasme hospital, Brussels

Ineke Vanlaere
Sarah Glorieux
Jean Francois Collard
Franky Sinap

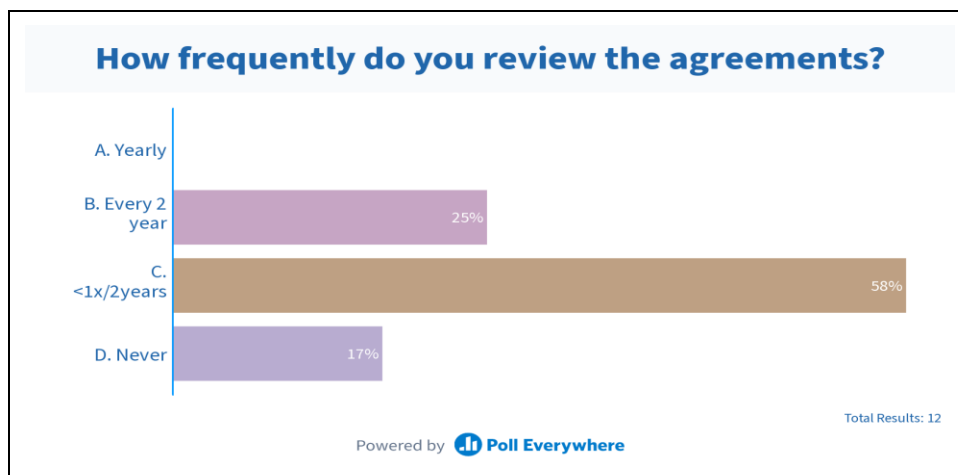
Dia 2



Dia 3



Dia 4



- EDQM: "These written agreements should be signed, dated and reviewed regularly (as defined by the parties concerned), but sooner if changes are required."
- JACIE: "Agreements shall be dated and reviewed on a regular basis, at a minimum every two (2) years."
- Most banks only review when a major change should be translated into the agreement.
- No uniformity in who has to sign. Try to avoid names in your agreement, rather work with addenda of the agreement to mention the responsible persons of your depot. The people who signed, must be notified about changes in the addendum. Also new signatures needed?
- It takes a lot of time to get the reviews and the signatures (very frustrating job)

JACIE standards : B4.6.1 Agreements shall be established with external parties providing critical services that could affect the quality and safety of the cellular therapy product or health and safety of the donor or recipient.

EDQM: To promote compliance with donor-selection criteria and procurement procedures, the TE must have written agreements with each person, clinical team or third-party procurement organization involved in carrying out procurement, as well as those collecting critical information used in donor selection

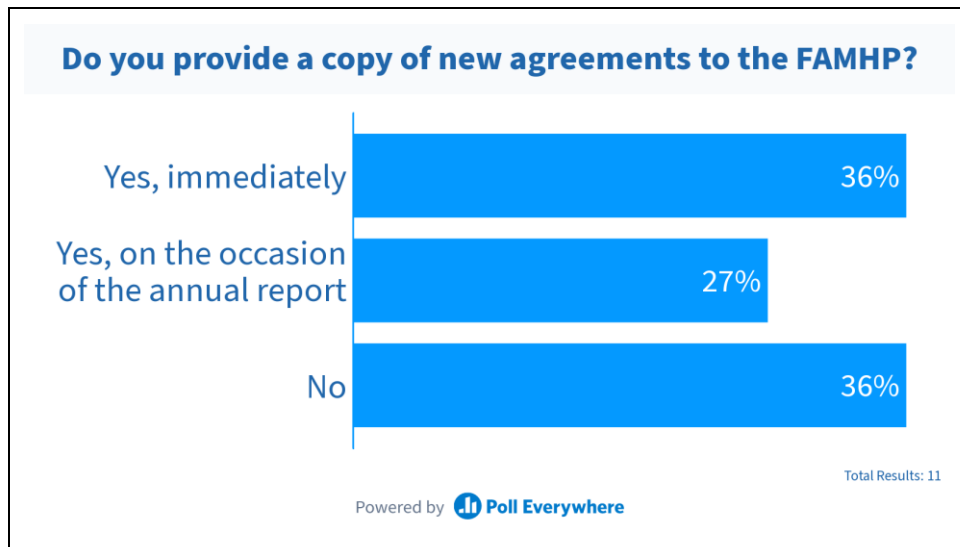
- **JACIE Standards:** B4.6.3 Agreements shall be dated and reviewed on a regular basis, at a minimum every two (2) years.
- **EDQM:** Agreements should be dated, reviewed and renewed on a regular basis

Dia 5



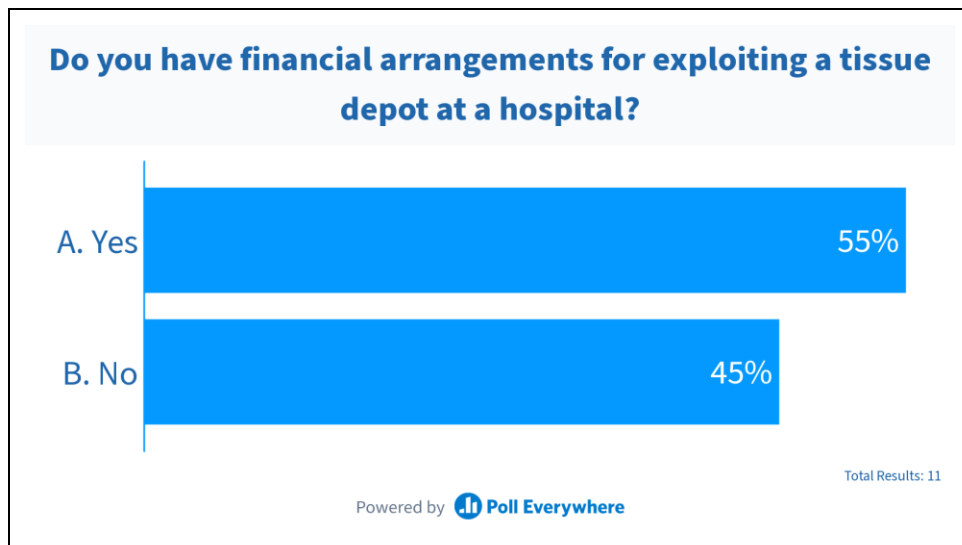
- Digital copy versus original copy? The original copy is always the best, in case of issues.
- One TE keeps a centralized digital copy (all procedures are centralized as well)

Dia 6



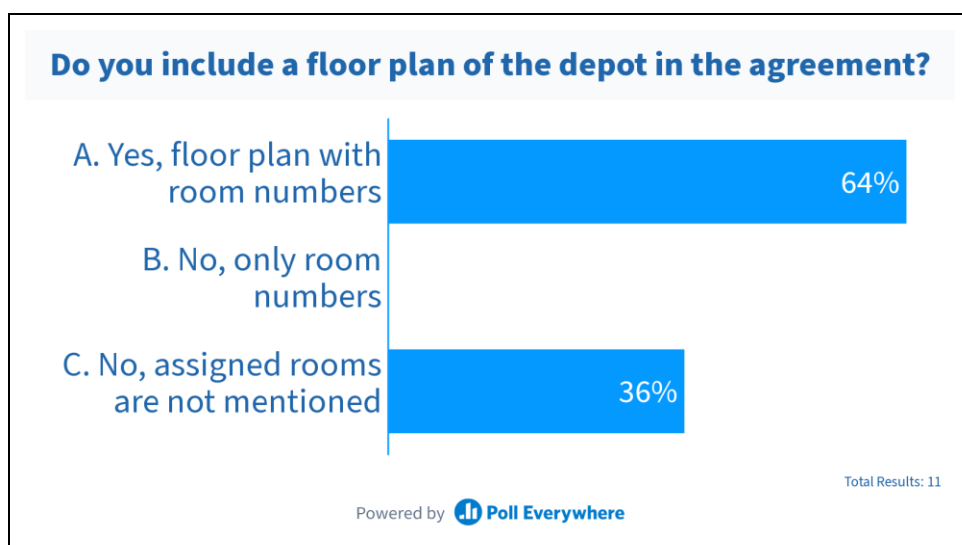
- FAMHP: This is not a change that requires mandatory reporting according to circular 551 (FAMHP), it is “desirable” that this is reported.
- Some banks send this with a yearly review of the SMF (with annual report), it is actually requested in the list of attachments of your site master file (provide a copy of each new agreement if not provided yet)

Dia 7



- There was confusion about this question. The depot activities are not charged by the TE. It's a favor for hospitals that also collect tissues for the TE.
- Financial agreements are made between the TE and the collection centers of femoral heads where the collection center receives an amount that varies from 0 € to 40€, 100€ and half of riziv/inami price. Some TEs only pay if everything was OK, including documentation. Other TEs only pay at the moment the tissue is transplanted. Other TEs wait for an invoice of the orthopedic surgeons. Some TEs only start paying after a minimum amount of prelevations is reached. Depending on the TE, the prices are premised for a collection as such, for a collection + complete file (questionnaire, sample, informed consent), for released femoral heads.
- It should be good to have an INAMI code for the prelevation itself, apart from the other steps in the tissue process.

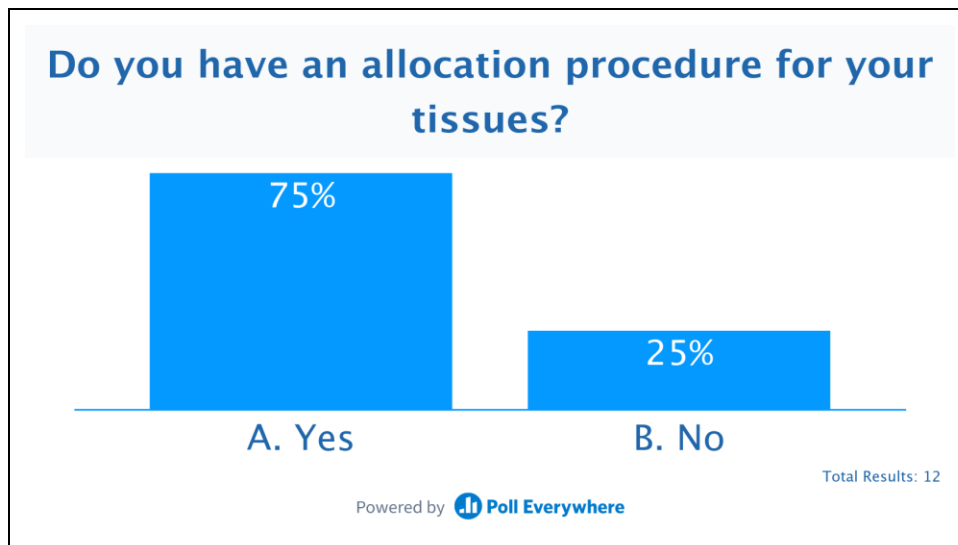
Dia 8



- A floor plan of the depot should be available.

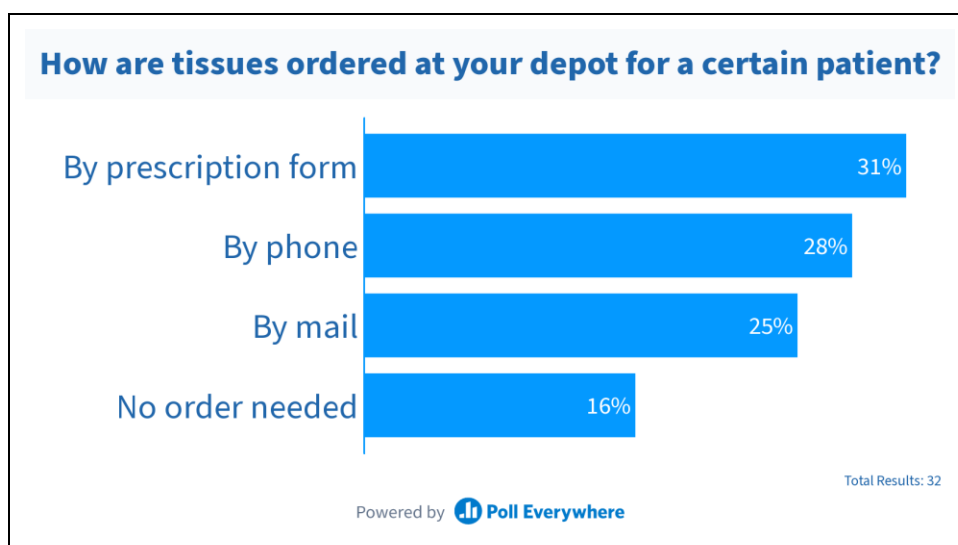


Dia 10



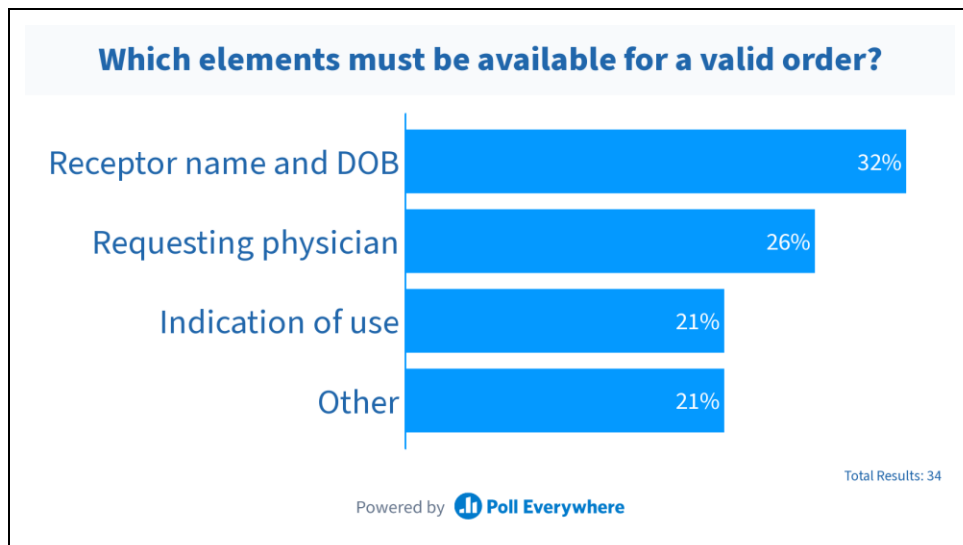
- An allocation procedure has to describe what you do in case of shortage of tissues. For cornea for instance. Which hospital > which patient will receive your last cornea tissue? One idea is that you stop replenishing your depots if your stock in the bank is too low. At that moment the TE manager is deciding about each use of the tissues.
- For musculoskeletal tissues, it seems only useful for specific types of bone / tendon with specific dimensions. There seems to be consensus about the fact that it makes no sense to have a strict allocation => the idea is not useful for musculoskeletal tissue.
- Certain banks use an allocation procedure, describing the following general guidelines:
 - A graft should be used at the site of the depot
 - A graft should be used by a physician
 - A graft should be used based on an approved indication (if not, approval needed by the TE manager)

Dia 11

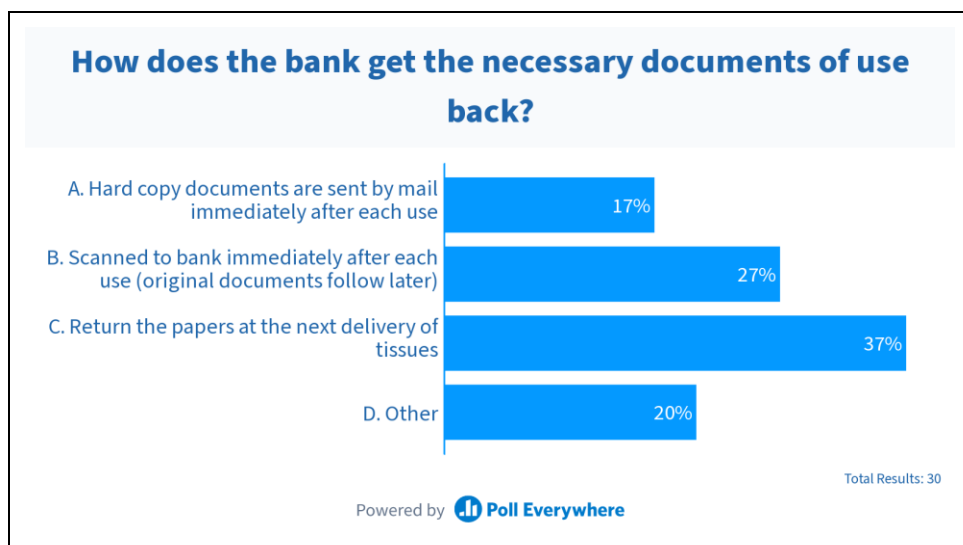


- Fax can also be used in some TEs.

Dia 12



Dia 13

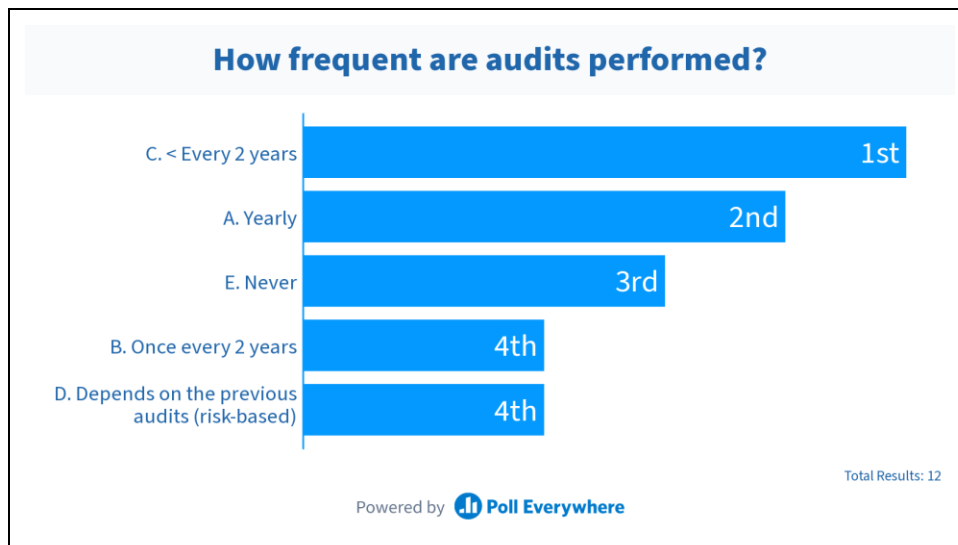


- One TE uses the cloud to share information (e.g. for medical release reports, register, log book, data T-monitoring, ...). Each depot has to upload the documents of use (no notification of upload to the TE). The hard copies are sent by post.
- One TE receives the paperwork at the moment of replenishment of the depot.
- A lot of reminders are being sent in order to receive all documentation. It's not easy for the TE employees to keep an overview.

Dia 14

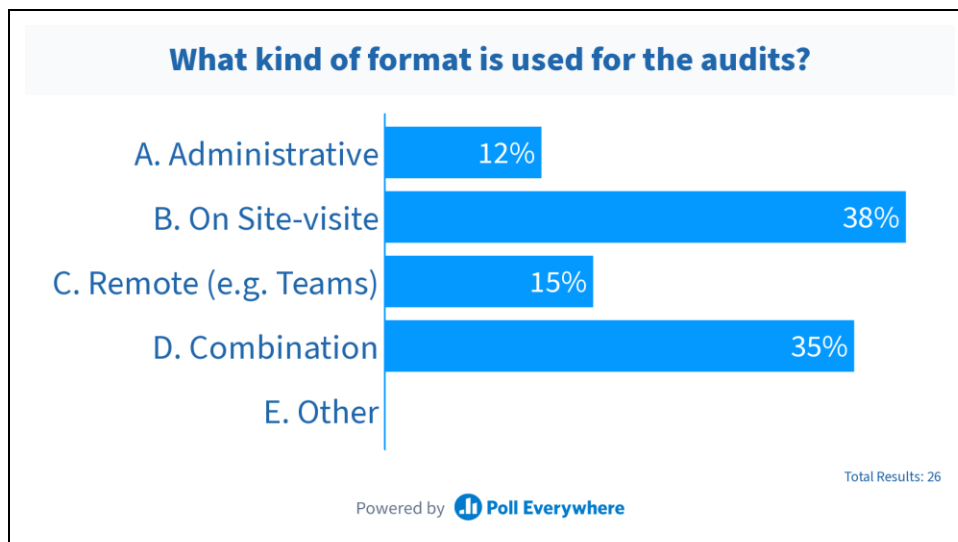


Dia 15



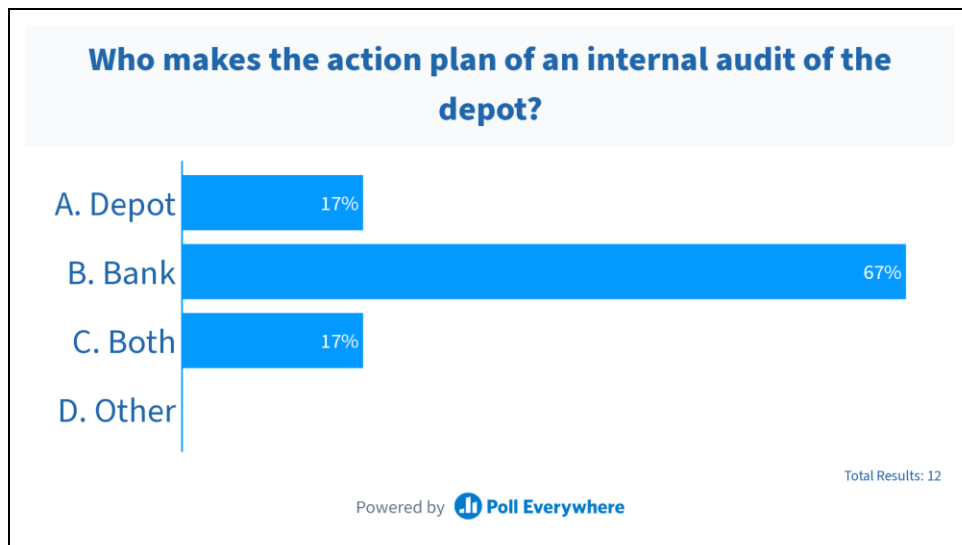
- Audits must be done on a regular basis.
- Suggestion: One can perform a risk assessment in order to determine the frequency, e.g. depending on the amount of grafts, only lyophilized grafts, non-conformities, compliance on previous audits. Document this assessment.

Dia 16



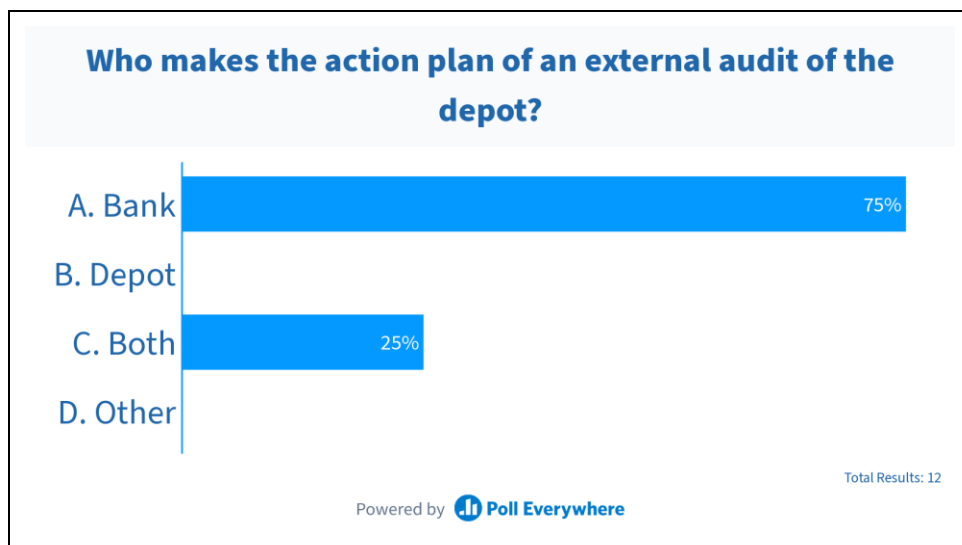
- Teams audits concern administrative, intermediate audits and can be used to alternate with on-site visits.
- One TE only performs an on-site visit when the remote audits are not OK. Other TEs yearly organize an on-site visit.
- In case of “badly” organized depots, the TE manager leads the audit. For the “good” depots, the quality manager can do this job.
- One TE really stopped the activities of a depot until all non-conformities are addressed. The problem is that these hospital also provide tissues to your TE...

Dia 17



- The answers to this question were interpreted differently. In general, the bank writes an audit report and defines guidelines/restrictions/actions within the report. However, the depot can propose/define how the actions are addressed, the bank needs to agree.

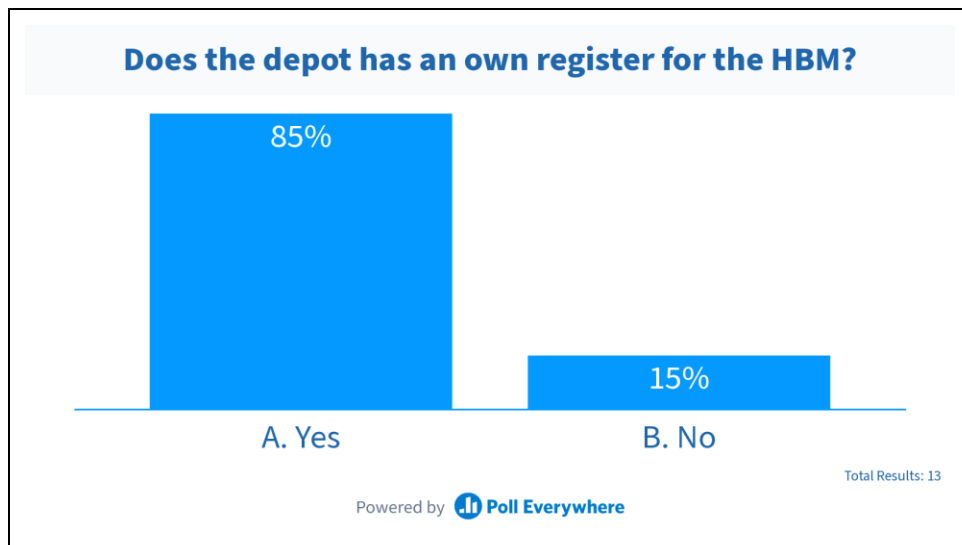
Dia 18



- 6 months seems to be a realistic and feasible deadline for the depots to perform actions. Remark: This also depends on the nature of the non-conformity (e.g. change the policy of your hospital versus small remark about a document)
- Suggestion for follow up: Perform a follow up via the documentation management system by setting a deadline every 2 months.
- Suggestion: immediately implement the preventive measures in all your depots. The FAMHP will request the same things in all depots.

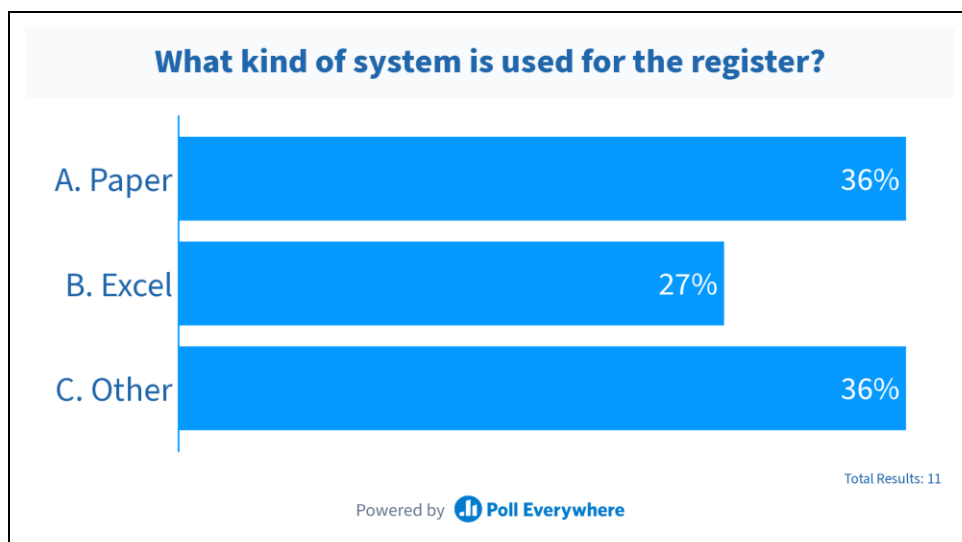


Dia 20



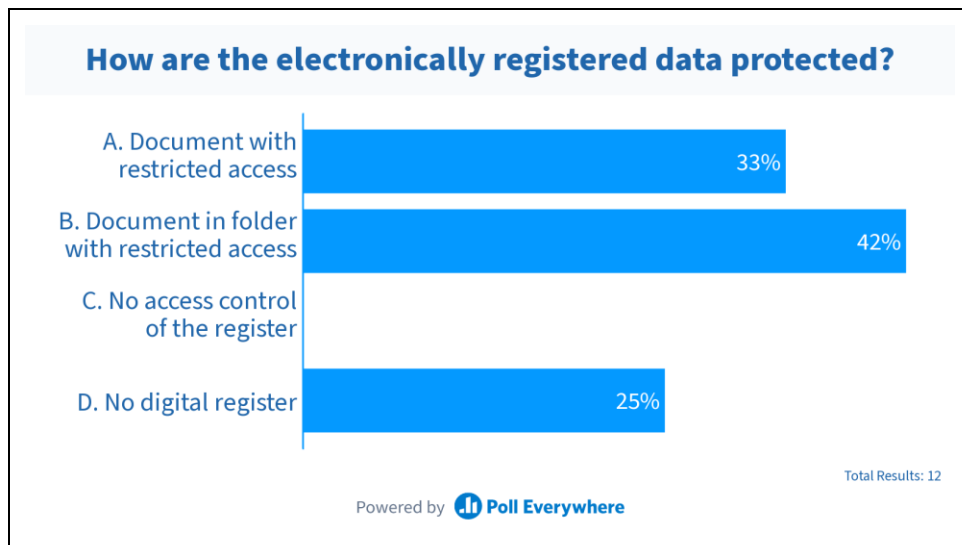
- The discussion shows that most depots have a file with the following data: Reference number of graft, date + time + person receipt, date + time + person delivery, recipient data. This file is called either “register” (but does not contain the full line as defined in the legislation) or “log book”. Most TEs keep a “Master register” at the bank which complies to the law, not at the depots (rather used to manage and crosscheck the inventory and traceability)

Dia 21



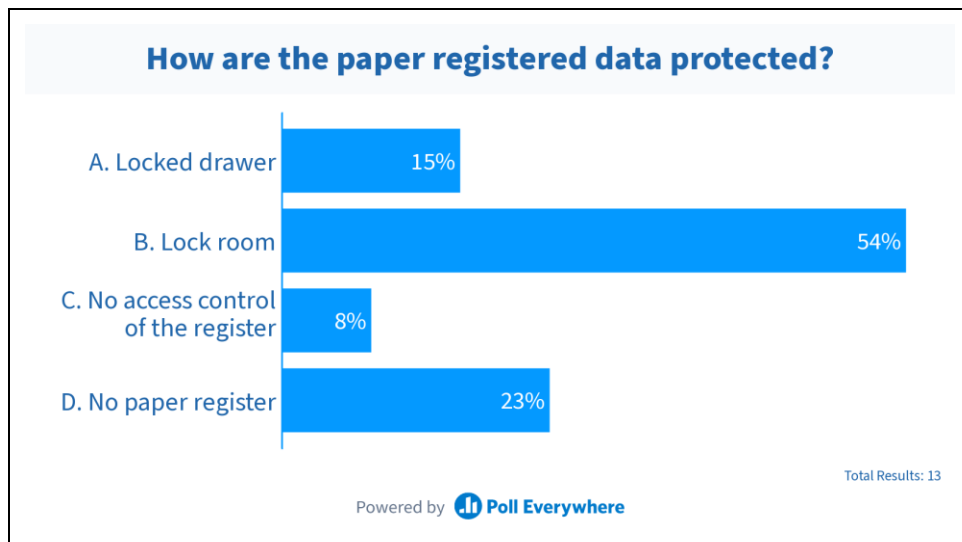
- One TE has a centralized register in the cloud where the depot personnel can register everything.

Dia 22



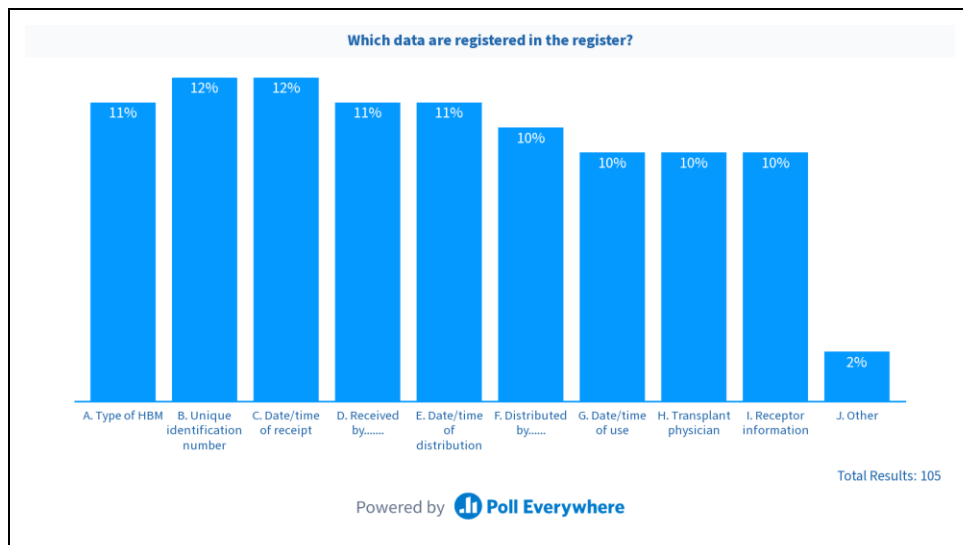
- For most depots, the general guidelines of the IT-department of the hospital are followed to obtain restricted access for the personnel of the depot: A protected file or folder is used. In some cases, there is only the controlled general access of the hospital (personal login).
- No checks have been performed to verify whether or not unallowed access occurred.

Dia 23



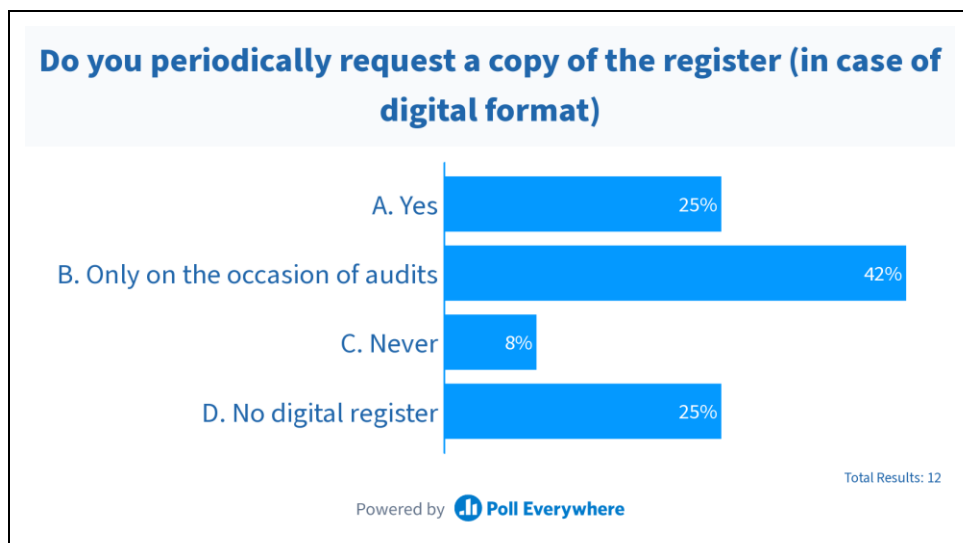
- Some TEs use different levels of protection.

Dia 24



- These data are laid down by law and should be registered.

Dia 25

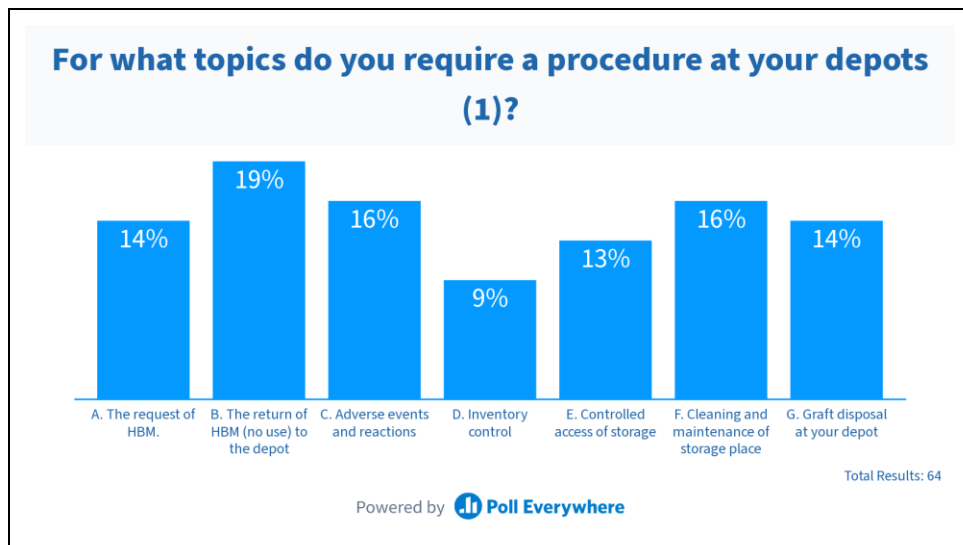


- Some TEs ask for a copy on monthly basis (this because of poor inventory management of some depots).

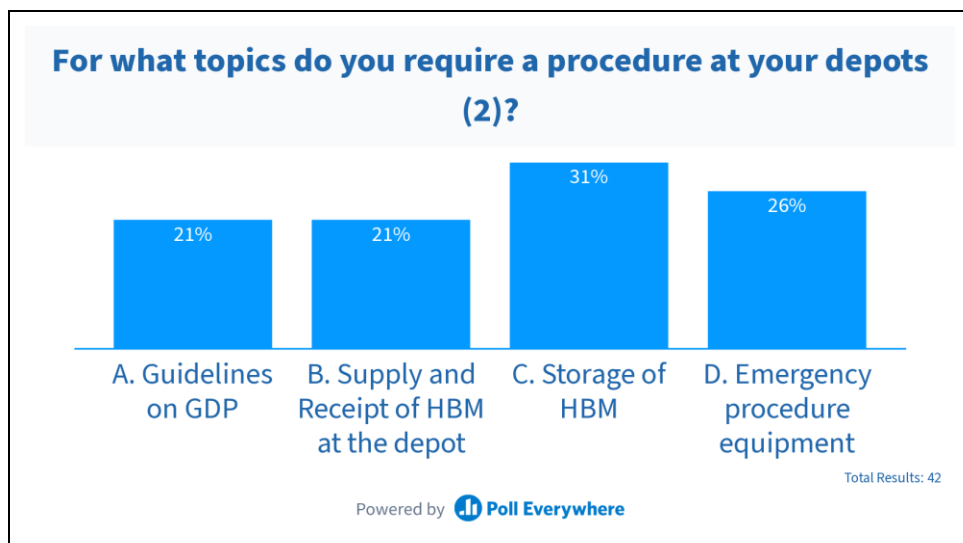
Dia 26



Dia 27

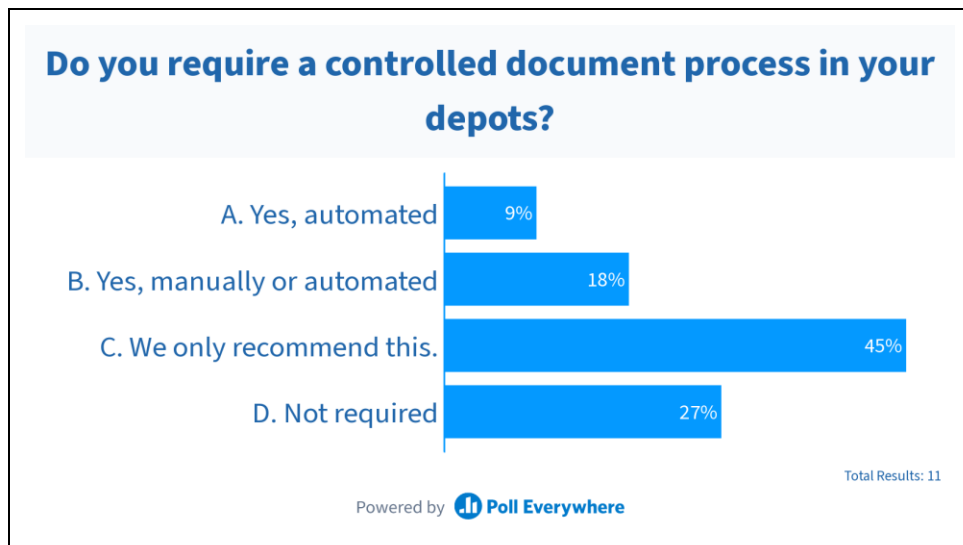


Dia 28



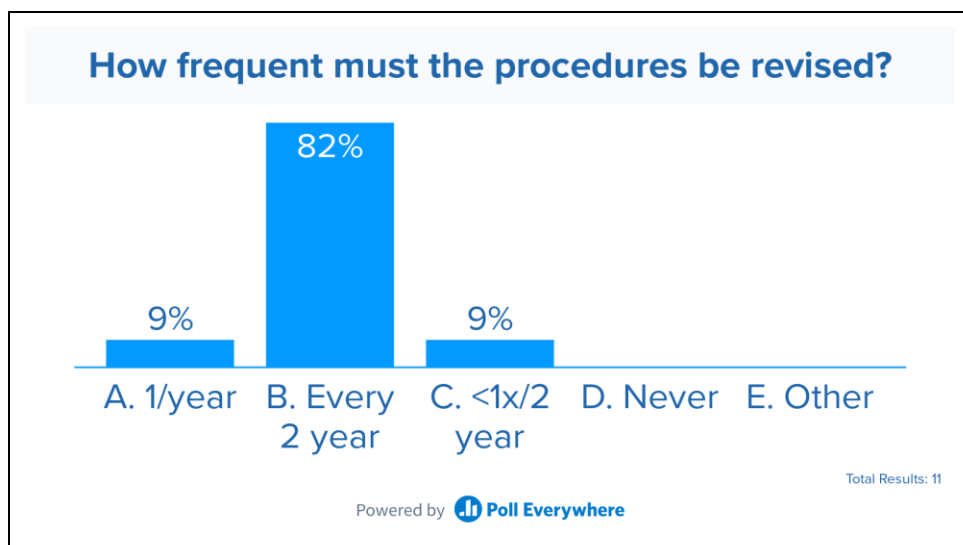
- These procedures are laid down by law and should be addressed for your depots (either in one procedure, several procedures)

Dia 29



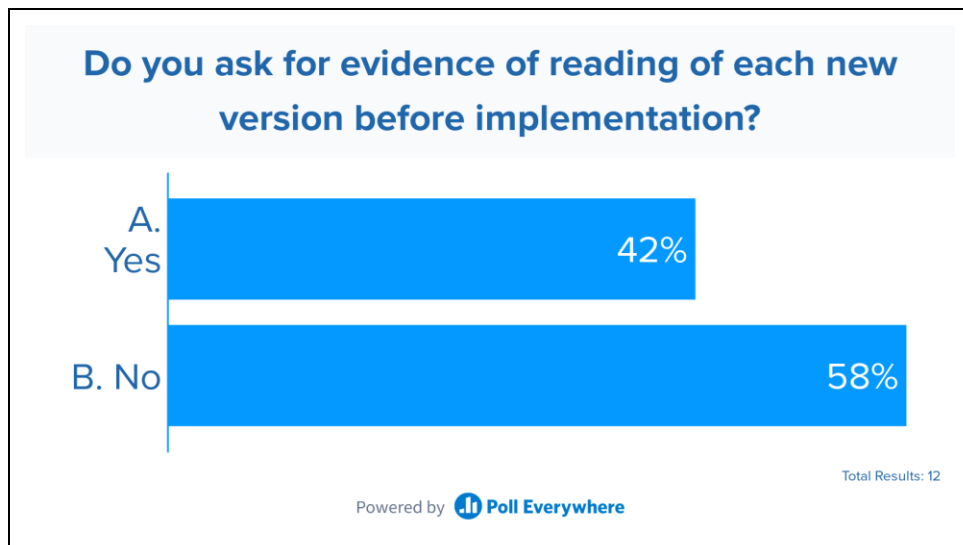
- It is difficult (not possible) to enforce this in other hospitals, even though we are convinced that it has added value.

Dia 30



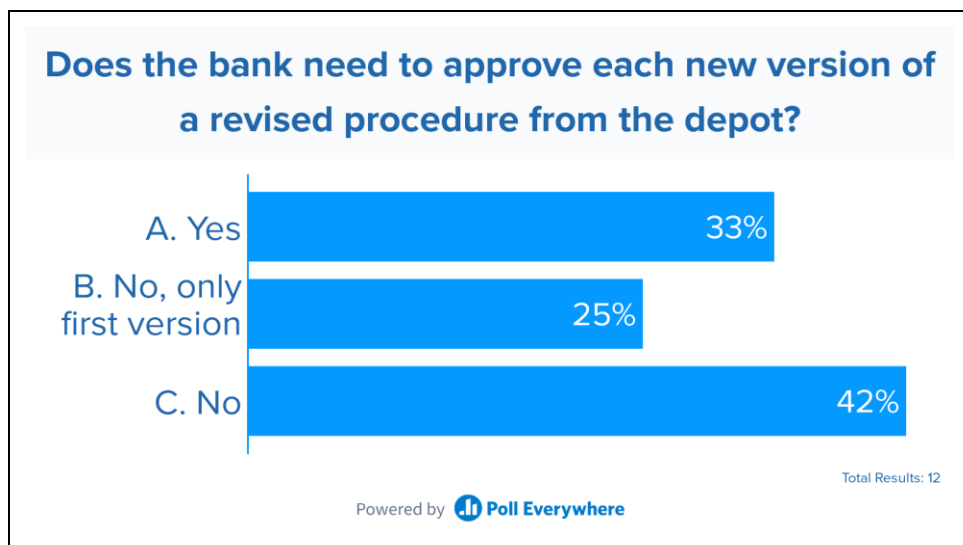
- Depending on the type of accreditation, there are different frequencies, e.g. JACIE requires a review every 2 years. Belgian law requires a “regular” review.

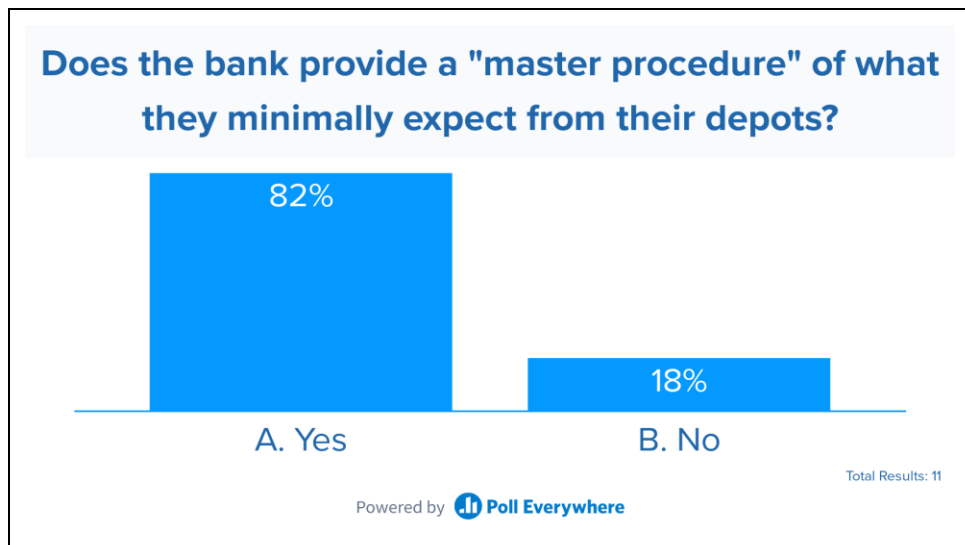
Dia 31



- The reading tasks can be followed up, e.g. a monthly overview can be obtained and verified.
- Other methods are used: An update of new versions of procedures are sent via email and/or are discussed in general meeting + report for evidence.

Dia 32





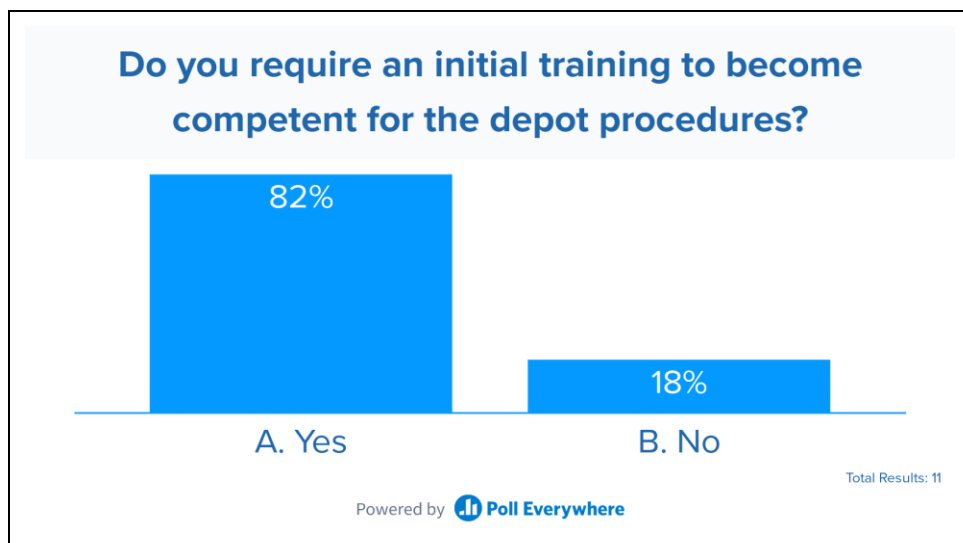


Dia 35



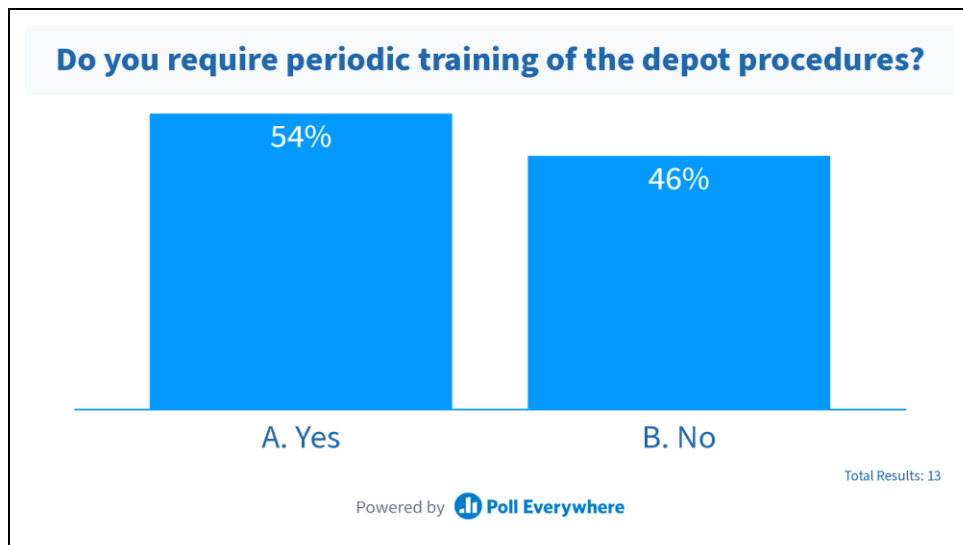
- A competency list is mandatory => See also discussion slide 38.

Dia 36



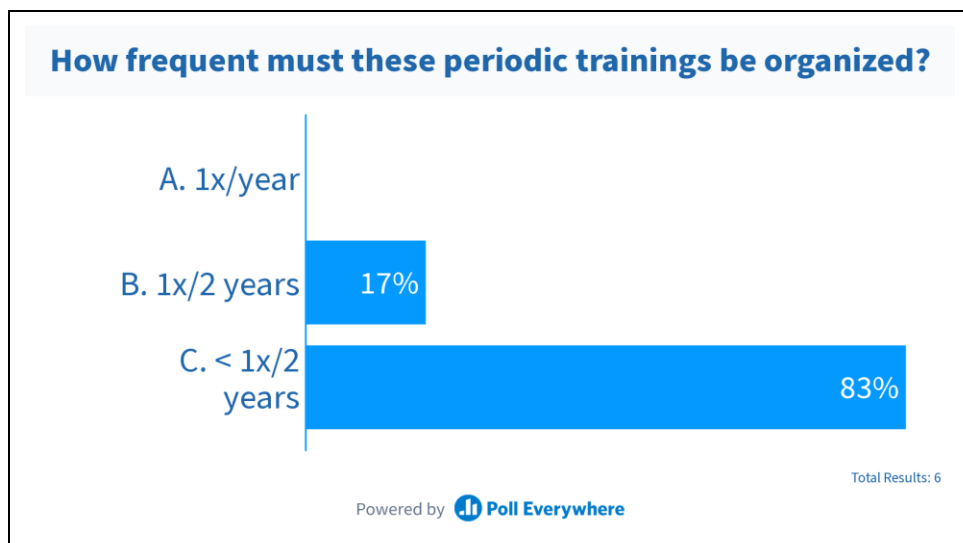
- The suggestion was made to add to the service level agreements that the responsible person of the depot is responsible for the training of the personnel and the competency list.

Dia 37



- In some depots, procedural changes are discussed in a general meeting + report.

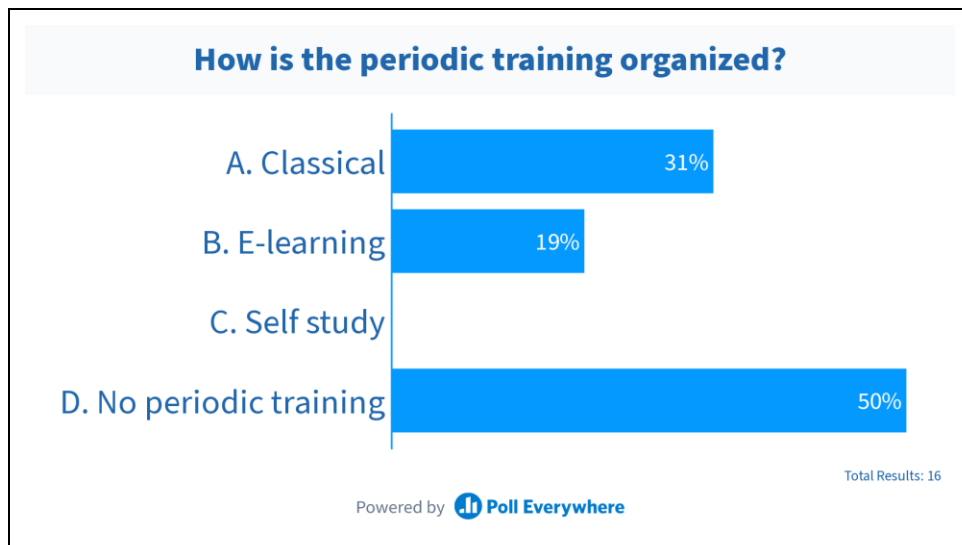
Dia 38



Relevant parts of the regulation are shown underneath:

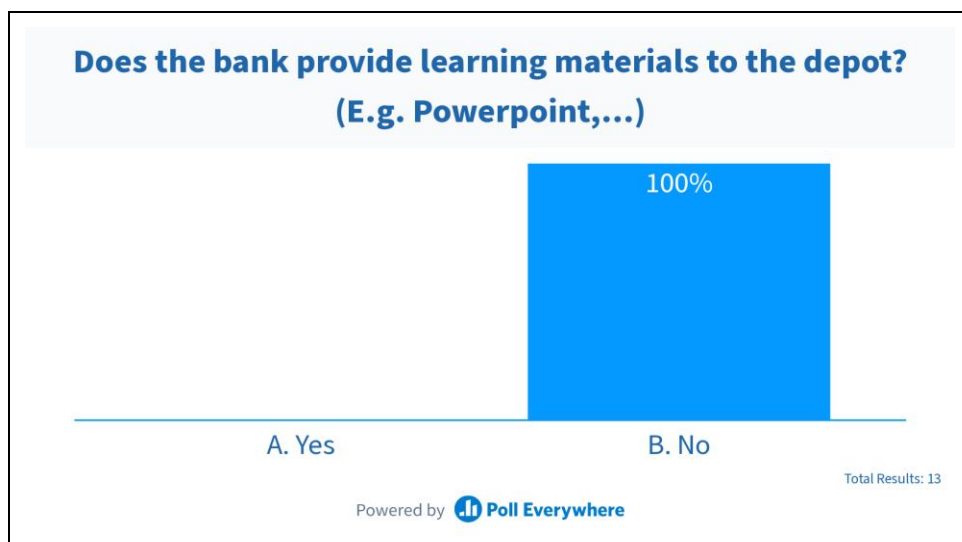
AGENCE FEDERALE DES MEDICAMENTS ET DES PRODUITS DE SANTE	FEDERAAL AGENTSCHAP VOOR GENEESMIDDELEN EN GEZONDHEIDSPRODUCTEN
F. 2009 — 3602 [C – 2009/18414]	N. 2009 — 3602 [C – 2009/18414]
28 SEPTEMBRE 2009. — Arrêté royal fixant les normes de qualité et de sécurité pour le don, le prélèvement, l'obtention, le contrôle, le traitement, le stockage et la distribution de matériel corporel humain, auxquelles les banques de matériel corporel humain, les structures intermédiaires de matériel corporel humain et les établissements de production doivent répondre	28 SEPTEMBER 2009. — Koninklijk besluit tot vaststelling van de kwaliteits- en veiligheidsnormen voor het doneren, wegnemen, verkrijgen, testen, bewerken, bewaren en distribueren van menselijk lichaamsmateriaal, waaraan de banken voor menselijk lichaamsmateriaal, de intermediaire structuren voor menselijk lichaamsmateriaal en de productie-instellingen moeten voldoen
<i>Section 3. — Personnel</i>	<i>Afdeling 3. — Personeel.</i>
Art. 5. Le personnel qui intervient directement dans le prélèvement, l'obtention, le traitement, la conservation, le stockage et la distribution de matériel corporel humain dans ou sous la responsabilité d'un établissement, doit posséder les qualifications nécessaires et doit recevoir à cet effet la formation nécessaire.	Art. 5. Het personeel dat rechtstreeks betrokken is bij het wegnemen, verkrijgen, bewerken, conserveren, bewaren en distribueren van menselijk lichaamsmateriaal in of onder verantwoordelijkheid van een instelling, dient over de nodige vakbekwaamheid te beschikken en hiervoor de nodige opleiding te krijgen.
B. Personnel	B. Personeel
1. Le personnel des établissements doit être disponible en nombre suffisant et être qualifié pour les tâches à effectuer. La compétence du personnel doit être évaluée à des intervalles appropriés, précisés dans le système de qualité.	1. Instellingen beschikken over voldoende personeel dat gekwalificeerd is voor de taken die het uitvoert. De bekwaamheid van het personeel wordt met passende tussenpozen, die zijn gespecificeerd in het kwaliteitssysteem, geëvalueerd.
2. Il doit exister des descriptions de poste claires, documentées et actualisées pour tous les membres du personnel. Leurs tâches, leurs fonctions et leur responsabilité doivent être clairement documentées et bien comprises.	2. Alle personeelsleden hebben een duidelijke, gedocumenteerde en actuele functieomschrijving. Hun taken, verantwoordelijkheden en verantwoordingsplicht zijn duidelijk gedocumenteerd en begrepen.
3. Le personnel doit bénéficier d'une formation de base et d'une formation de mise à jour lorsqu'une modification des procédures ou une évolution des connaissances scientifiques l'exige, et se voir offrir des propositions appropriées de perfectionnement professionnel dans le domaine considéré. Le programme de formation assure et prouve par des documents que chaque individu :	3. Het personeel krijgt een basisopleiding, de nodige bijscholing bij verandering van de procedures of ontwikkeling van de wetenschappelijke kennis en geschikte mogelijkheden voor verdere relevante beroepsontwikkeling. Het opleidingsprogramma waarborgt en documenteert dat elk individu :
a) a apporté la preuve de sa compétence dans l'exécution des tâches qui lui sont assignées;	a) over aantoonbare bekwaamheid beschikt voor het uitvoeren van zijn aangewezen taken;
b) possède une connaissance et une compréhension adéquates des principes et/ou des processus scientifiques et/ou techniques qui sont importants pour les tâches qui lui incombent;	b) beschikt over voldoende kennis van en inzicht in de wetenschappelijke en/of technische processen en principes die van belang zijn voor zijn aangewezen taken;
c) comprend le cadre organisationnel, le système de qualité et les règles de santé et de sécurité de l'établissement dans lequel il travaille;	c) inzicht heeft in het organisatorische kader, het kwaliteitssysteem en de gezondheids- en veiligheidsvoorschriften van de instelling waar het werkzaam is;
d) est dûment informé du contexte éthique, juridique et réglementaire plus large dans lequel son travail s'inscrit.	d) voldoende geïnformeerd is over de ruimere ethische, juridische en wettelijke context van zijn werkzaamheden.

Dia 39

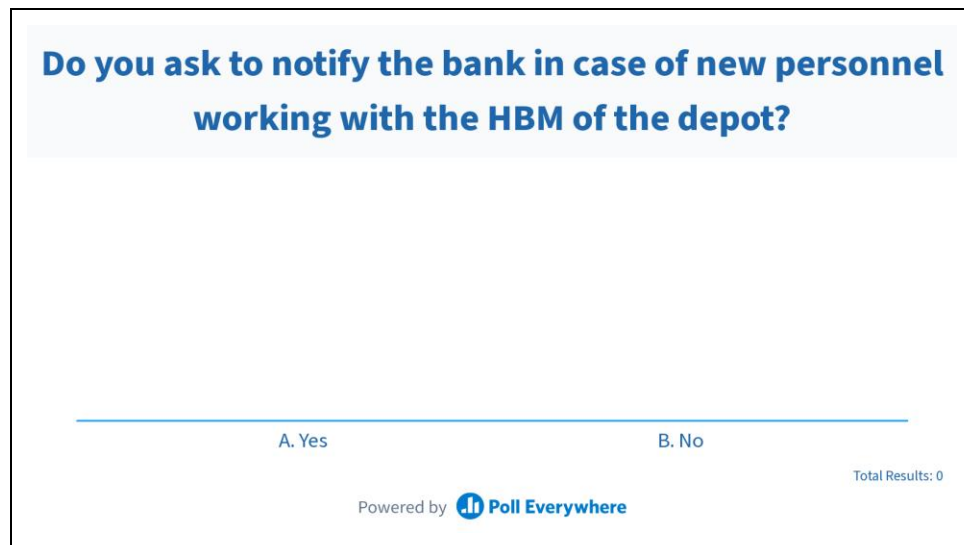


- Some TEs started with elearnings. This can save time and money. Easier for the depots and the TEs. Always the same information is given during the training.
- But elearning also takes a lot of time to develop. And also to follow-up (who has done the e-learning, who failed, who was passed the test,...). This is only feasible if the hospitals has an e-learning platform (not always accessible for external persons=depot personnel)

Dia 40




Dia 41



- No. Comes up during audits. Only a change in the responsables shall be notified.

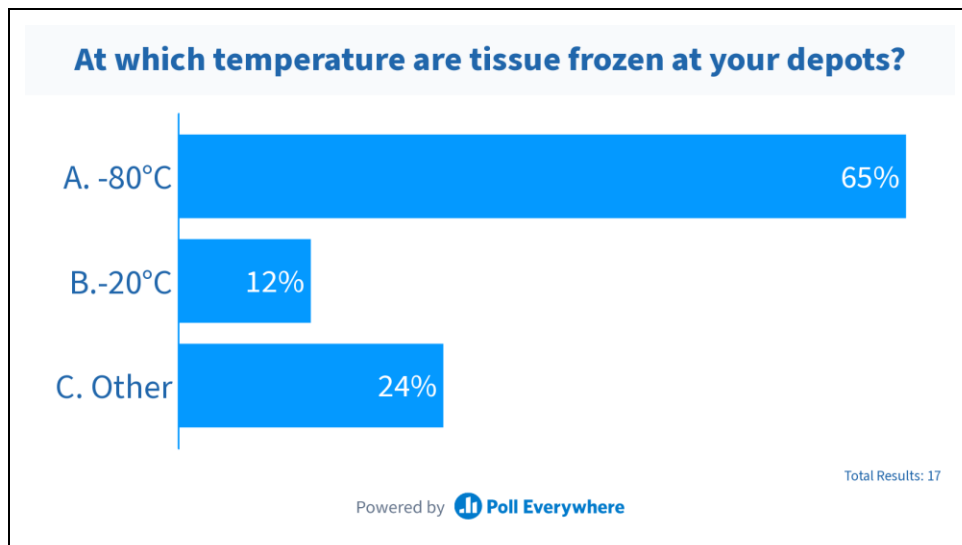
STORAGE



WORKSHOP BVM
42
01 JUNE 2023

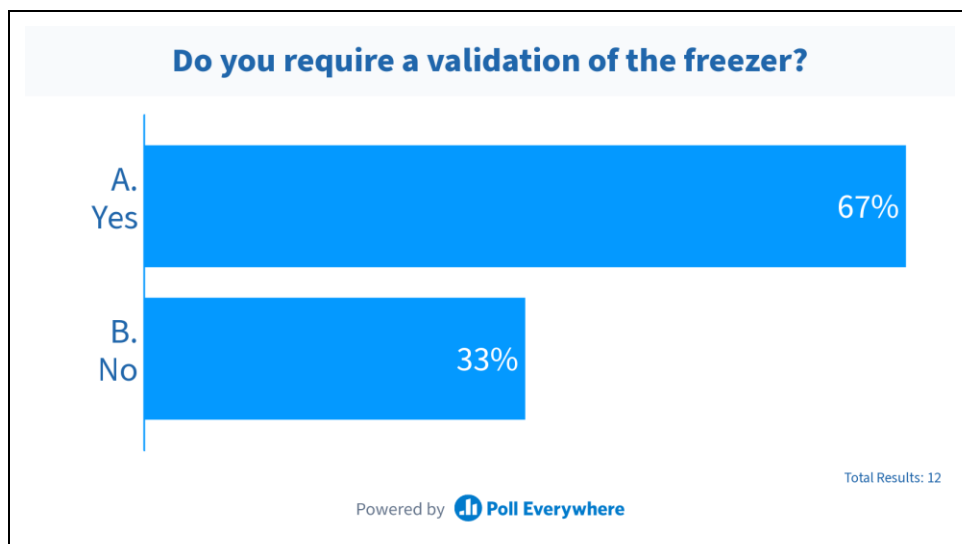
The image features a dark purple background. On the left side, there is a large, stylized spiral graphic composed of alternating red and blue lines. In the center-right, there is a rectangular inset showing a thermometer. The thermometer has a white face with black markings and a red needle pointing to approximately -15°C. The background of the thermometer inset is a light blue, cloudy sky. On the right side of the purple background, there is vertical text in white: 'WORKSHOP BVM', '42', and '01 JUNE 2023'.

Dia 43



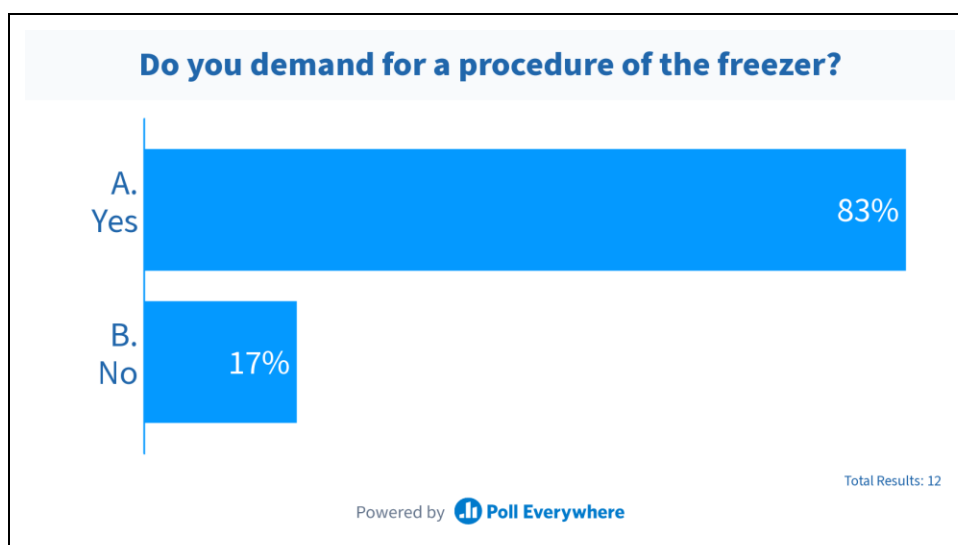
- Remark for -20°C => this was selected for those cases where collected femoral heads can be stored at -20°C degrees during max. 1 month before those grafts will be lyophilized.
- Other: e.g. formaldehyde

Dia 44



- In those TEs where a validation is required, only an IQ/OQ is used. No mappings are performed.
- Yes for new freezers. Old ones are validated by “historical use without problems”.

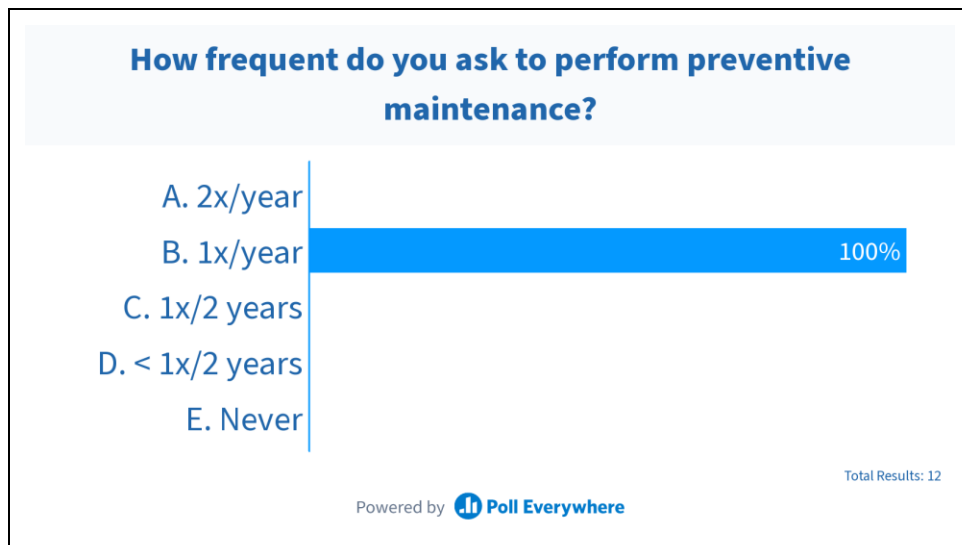
Dia 45



Dia 46

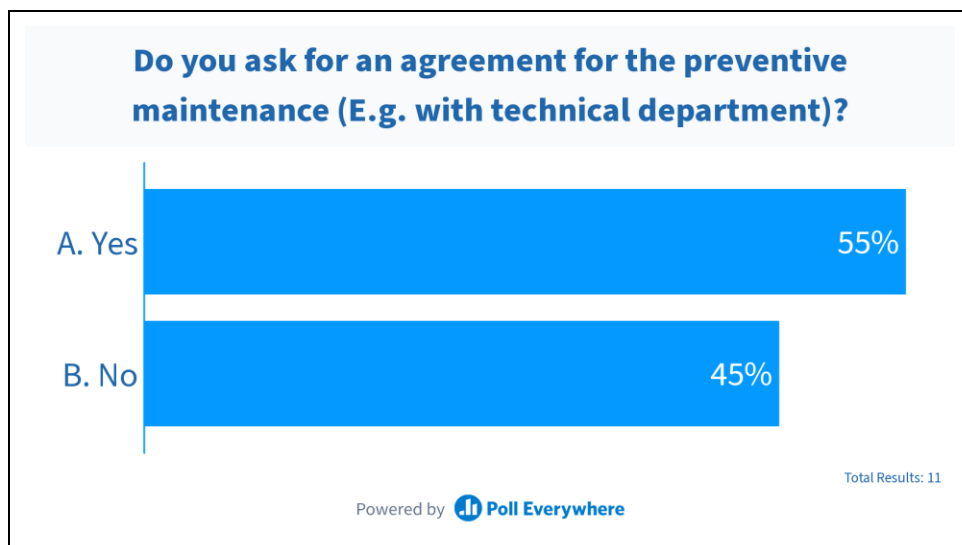


Dia 47



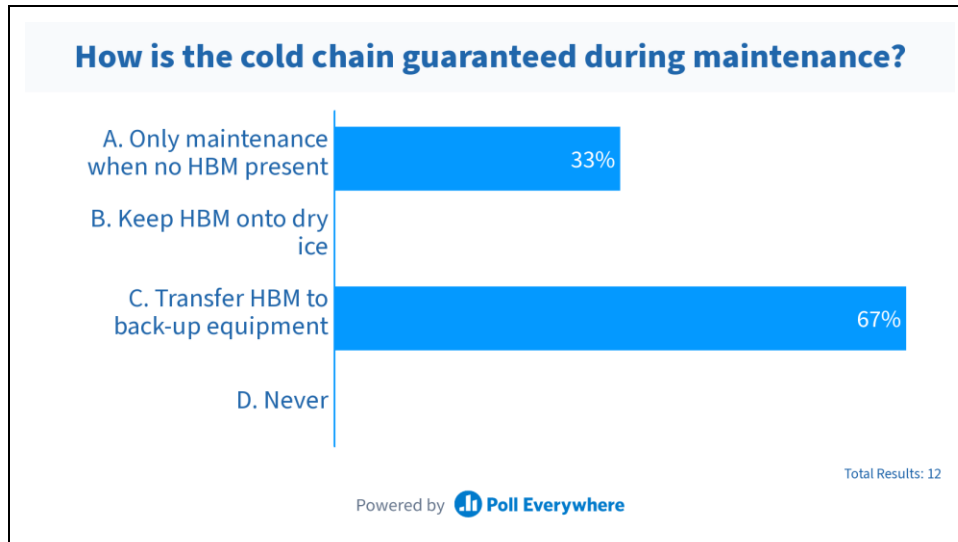
- No uniformity about what is understood under “manintenance”. Some defrost freezer, some only remove ice, some only clean the fans,...

Dia 48

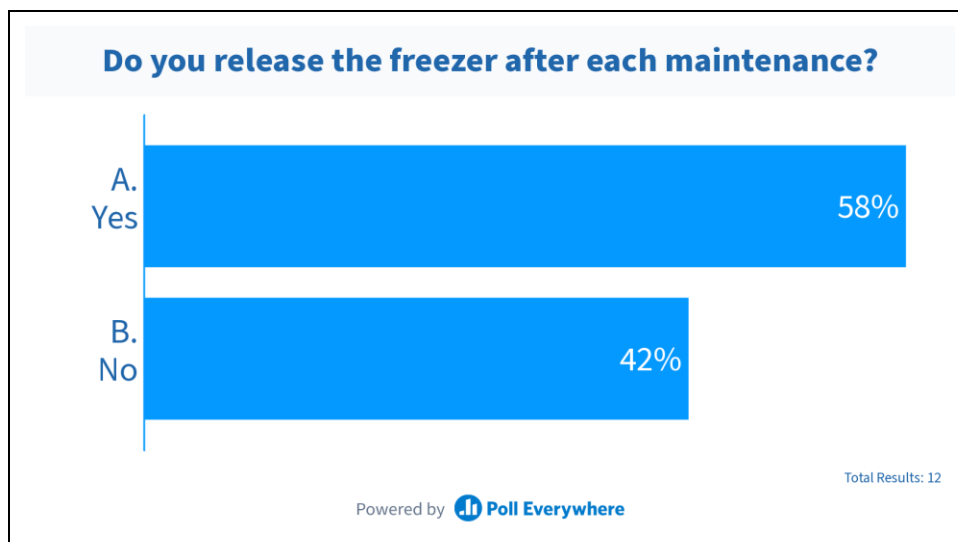


- During audits, most TEs ask for an agreement; however, this agreement is rather recommended than mandatory? (storage however is a critical step...). The yearly maintenance on the other hand is mandatory.

Dia 49

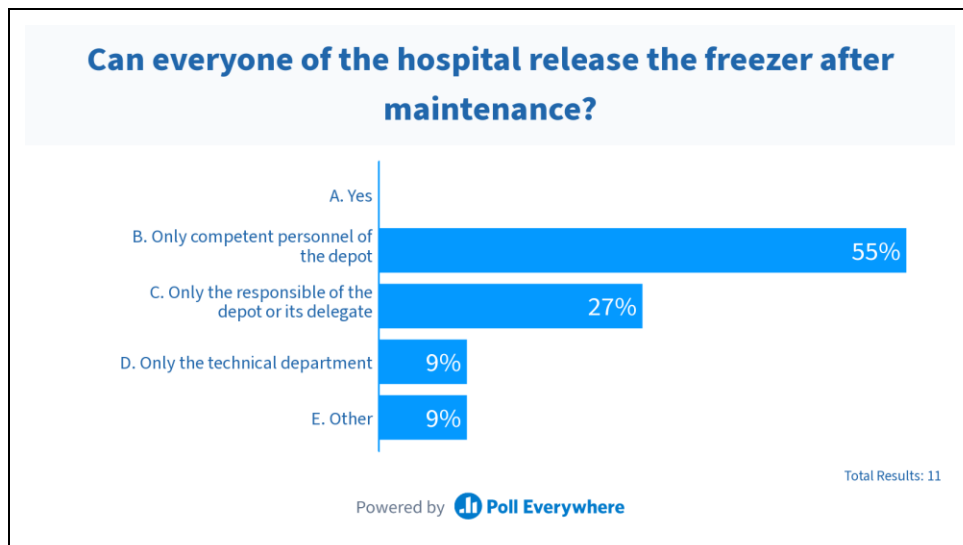


Dia 50

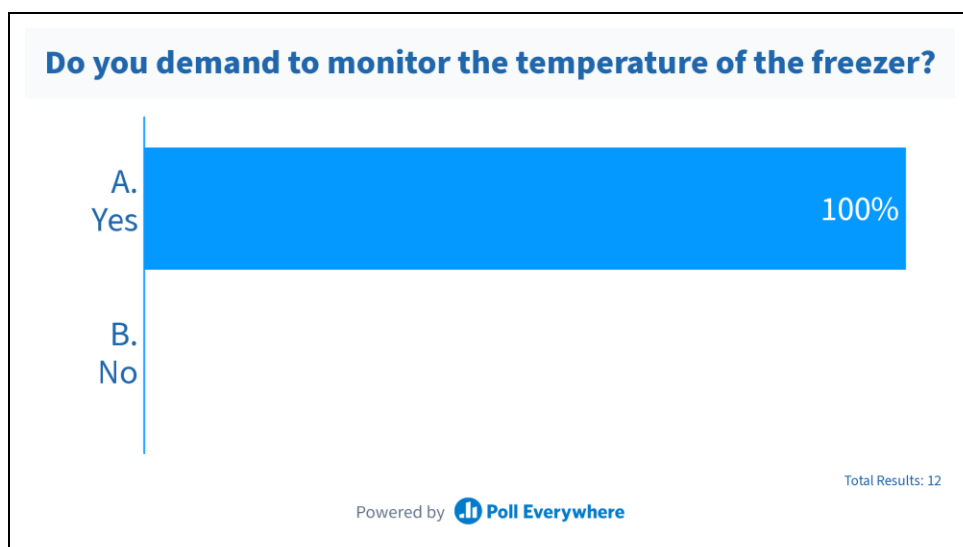


- Several TEs got a remark from the FAGG inspectors to release the freezer after maintenance. They refer to the KB Quality addendum VII C3. Thus, Yes, we shall do a release of the freezer.

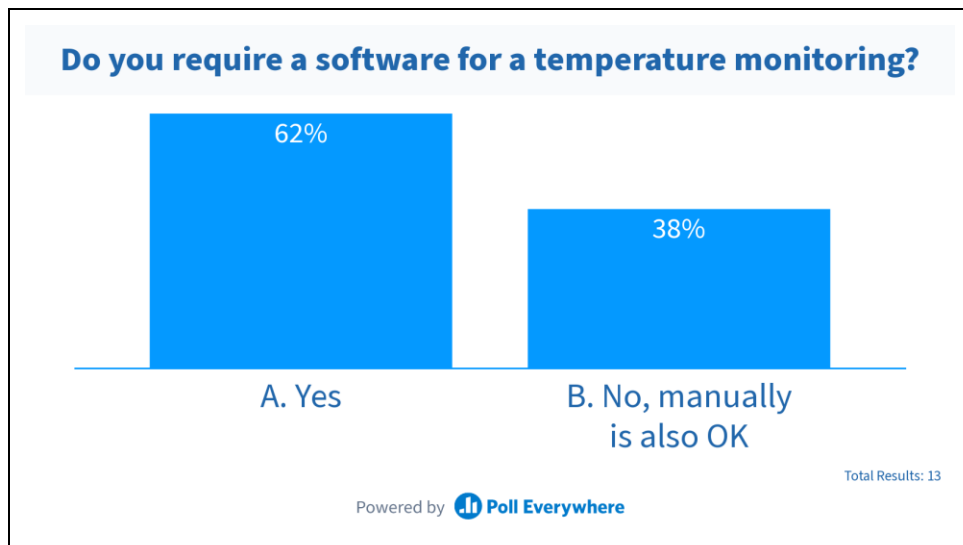
Dia 51



Dia 52



Dia 53

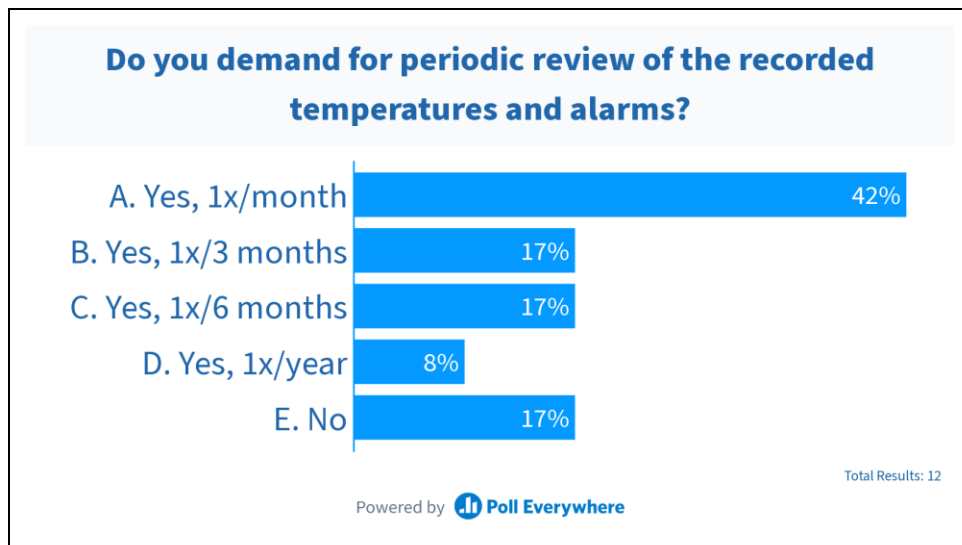


- Is difficult to enforce this in other hospitals. But most TEs recommend it.

Dia 54

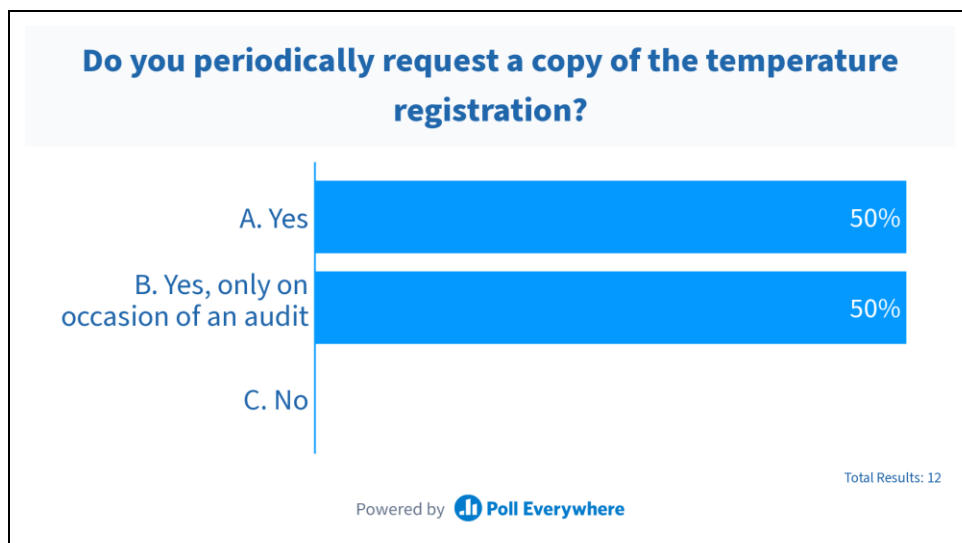


Dia 55



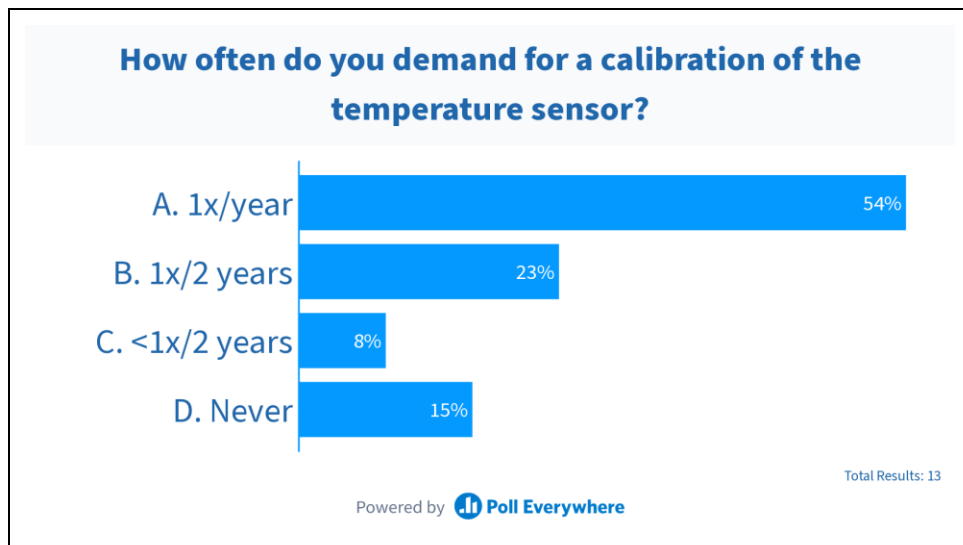
- If the alarm immediately goes to personnel of the TE, a periodic review is not necessary. If a central system of the hospital is used (e.g. technical department) a review is a good practice to check adequate response.

Dia 56

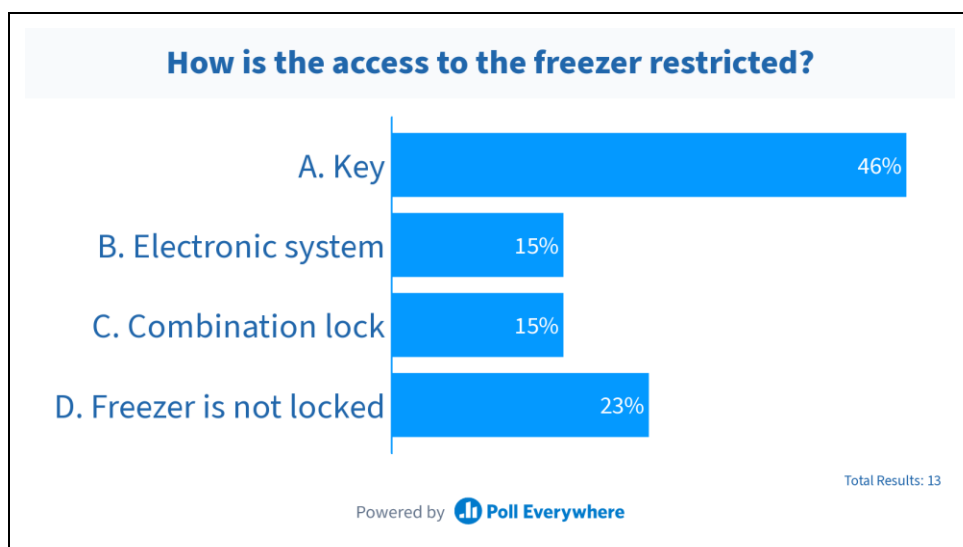


- Some TEs request these data every 6 months, other every month, other only during audits

Dia 57

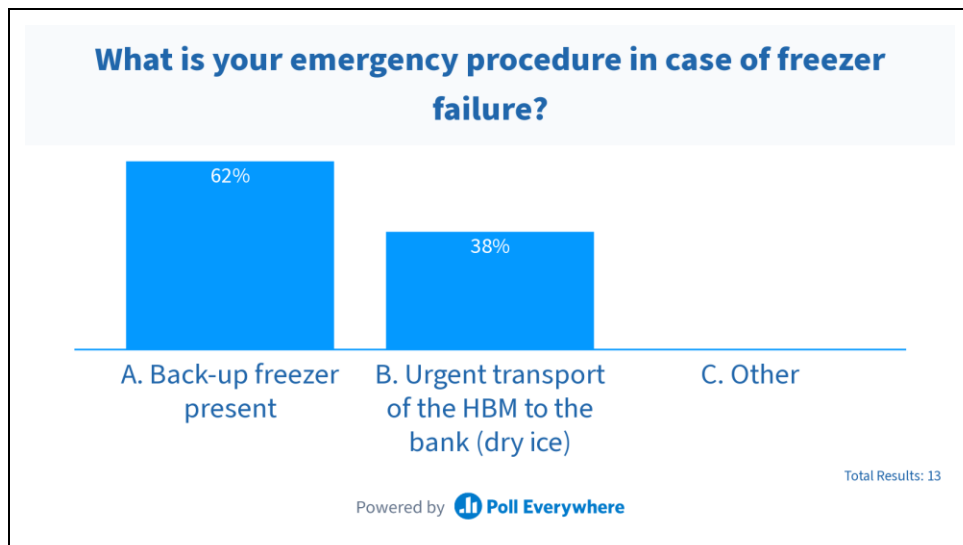


Dia 58

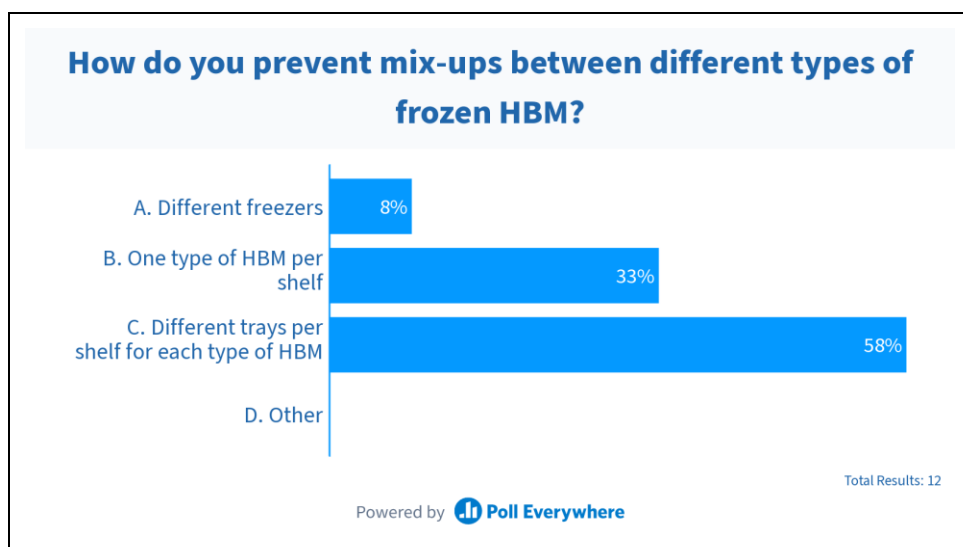


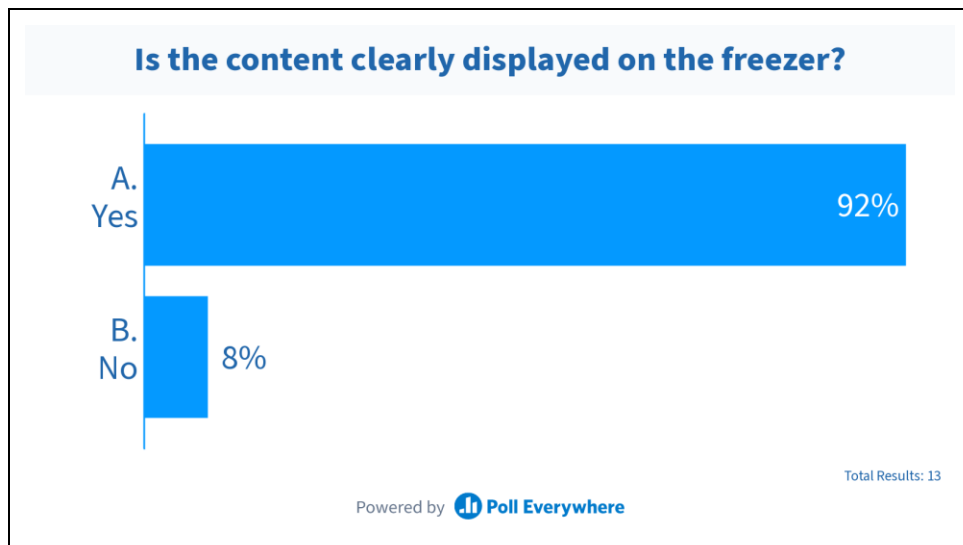
- Some TE's got a remark during a FAGG inspection that a key box with code should be present while in other cases the restricted access via badge control is sufficient. It is questioned how we should control access => advice from SHC?

Dia 59



Dia 60





LYOPHILIZED TISSUE



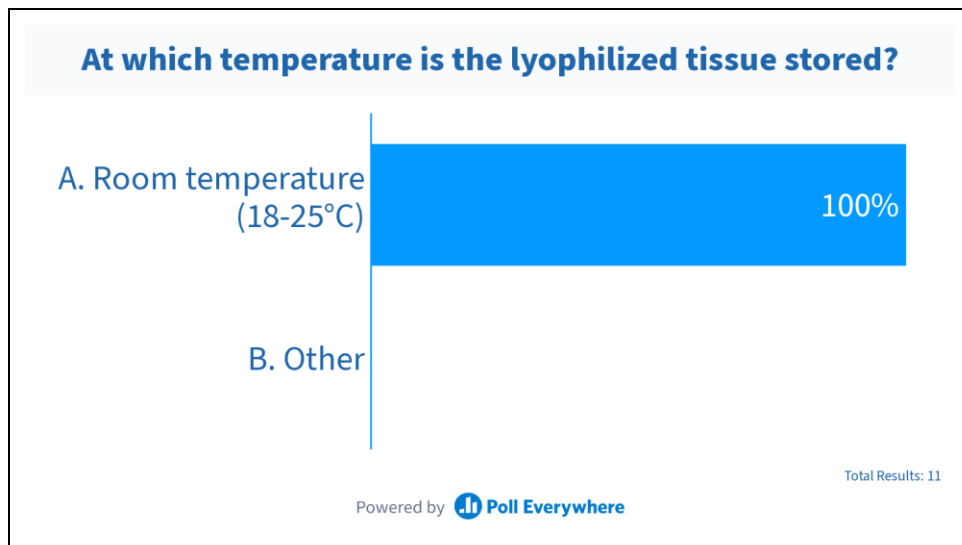
The image shows four glass vials with blue caps, each containing a white, lyophilized tissue sample. The vials are arranged in a row on a dark surface. The background of the slide is dark purple with a stylized graphic of a globe or sphere composed of red and blue lines on the right side.

WORKSHOP BYWB

62

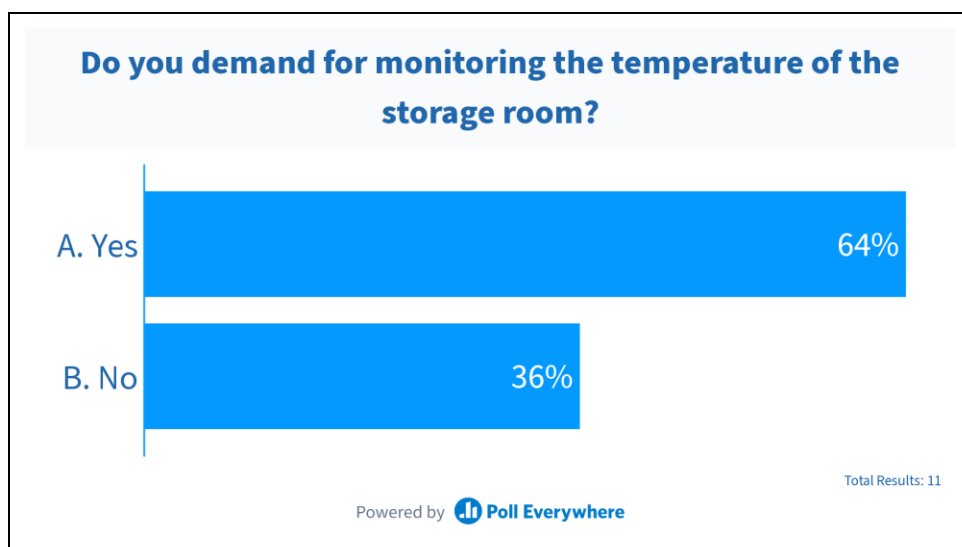
01 JUNE 2023

Dia 63



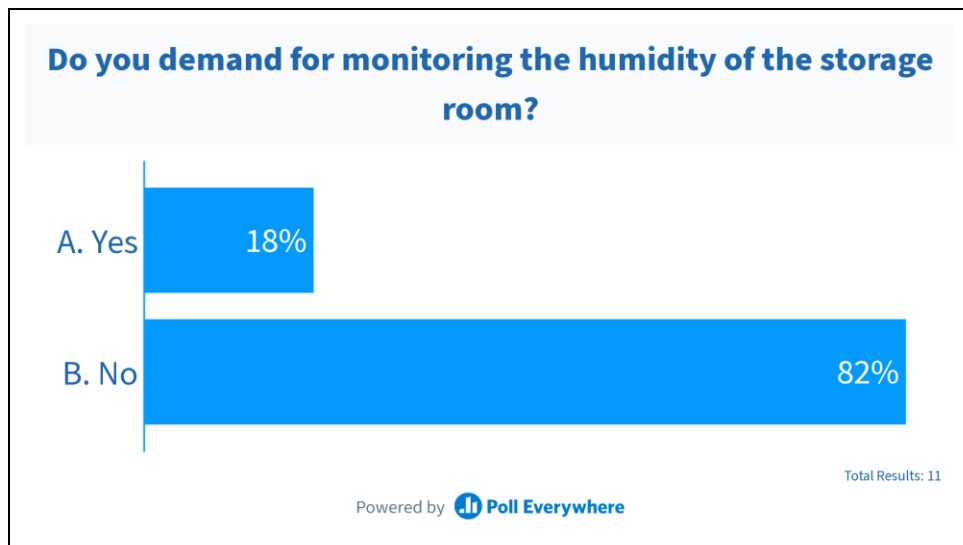
- According to some members, the lower criterium is not necessary. No problem to store below 18°C.

Dia 64



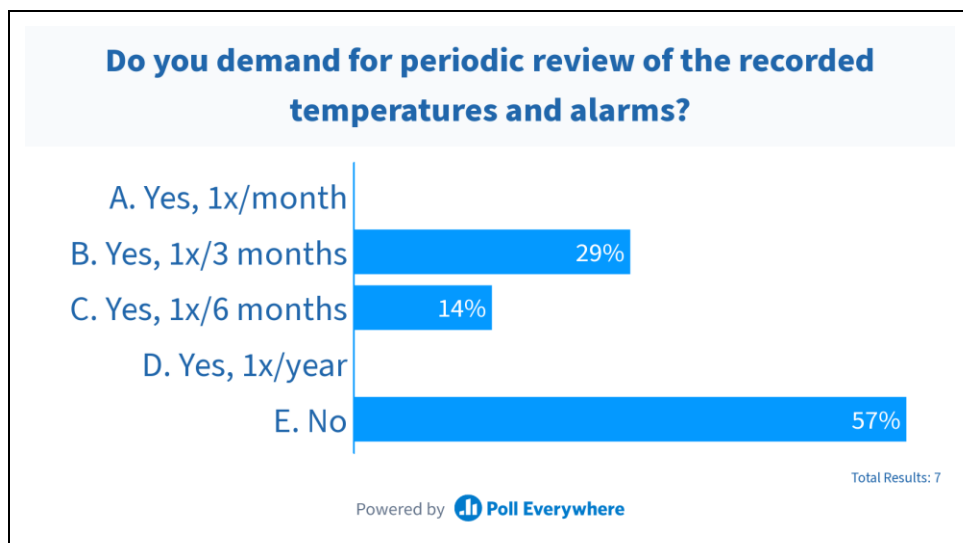
- There are no data available indicating that the temperature could have an impact on the quality of the grafts.
- A publication exists stating that no modifications of the bone structure occur below 47°C. Based on a risk assessment, the possible impact of the ambient temperature on lyophilized tissue can be evaluated. Furthermore, advice could be asked to the SHC?

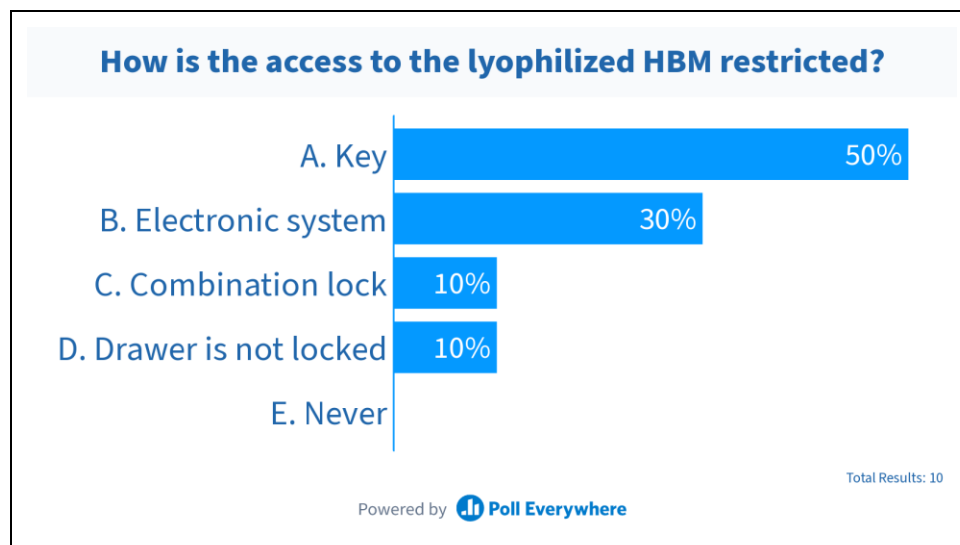
Dia 65



- The packages are sealed => humidity cannot have any impact / a risk assessment can be performed.

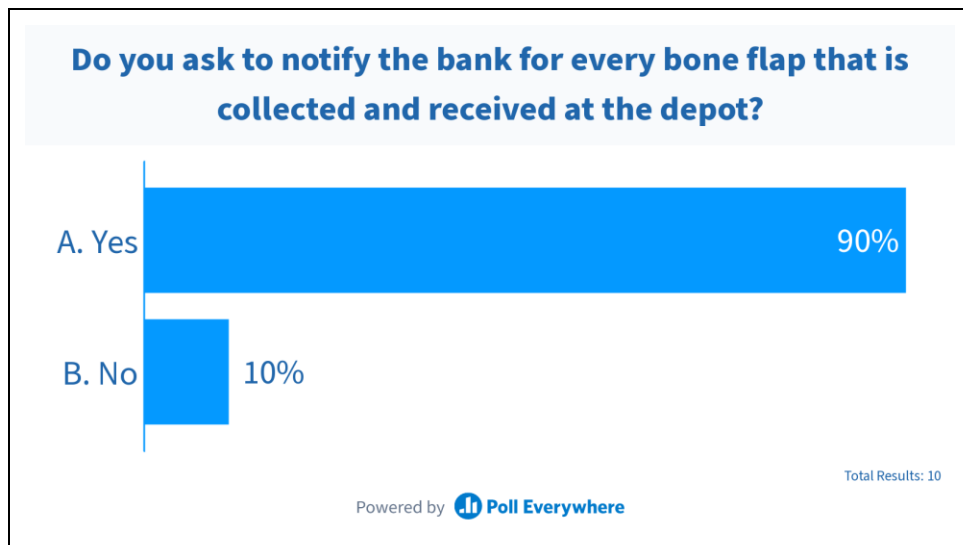
Dia 66





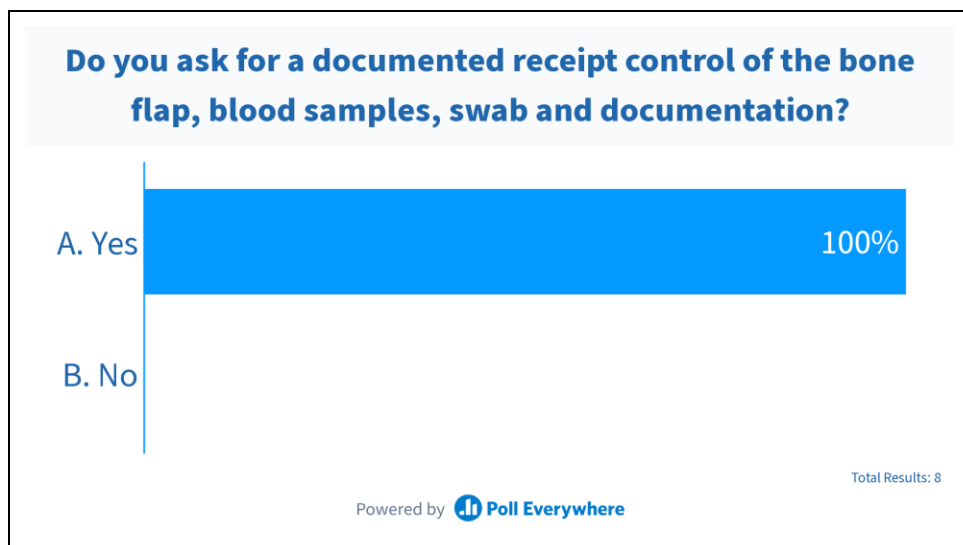


Dia 69

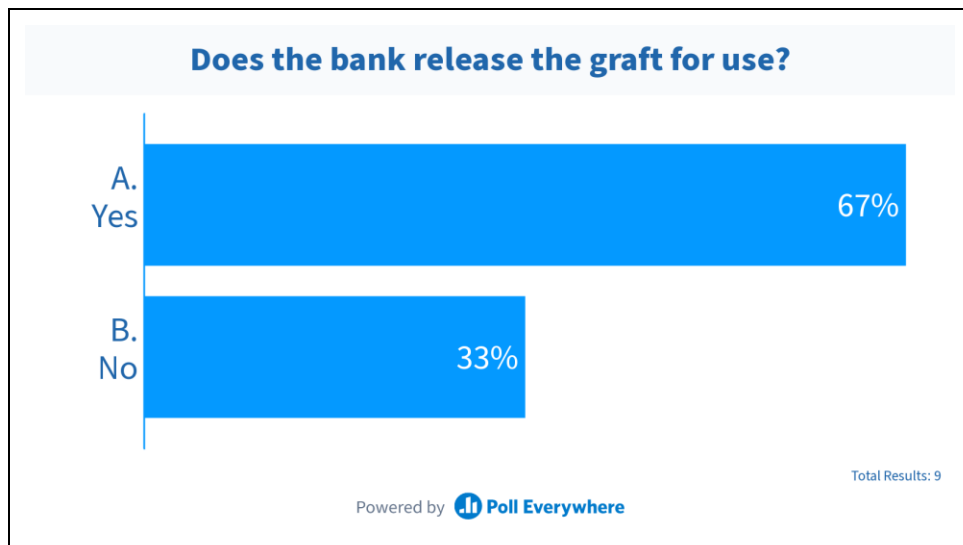


- Some TEs bring the bone flaps to the TE. Other TEs have agreements with the collection centre to store them locally (practical reasons: transplantation is sometimes faster than the transport).

Dia 70

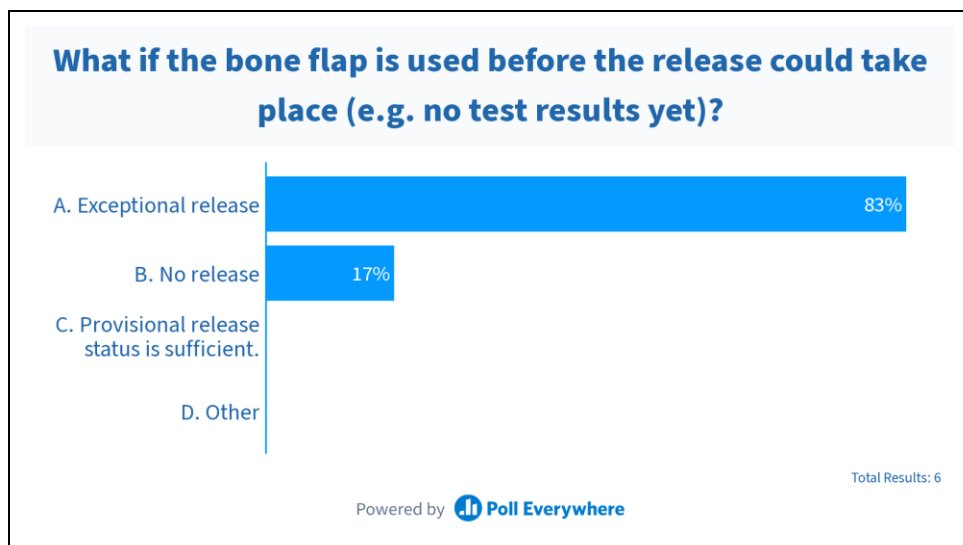


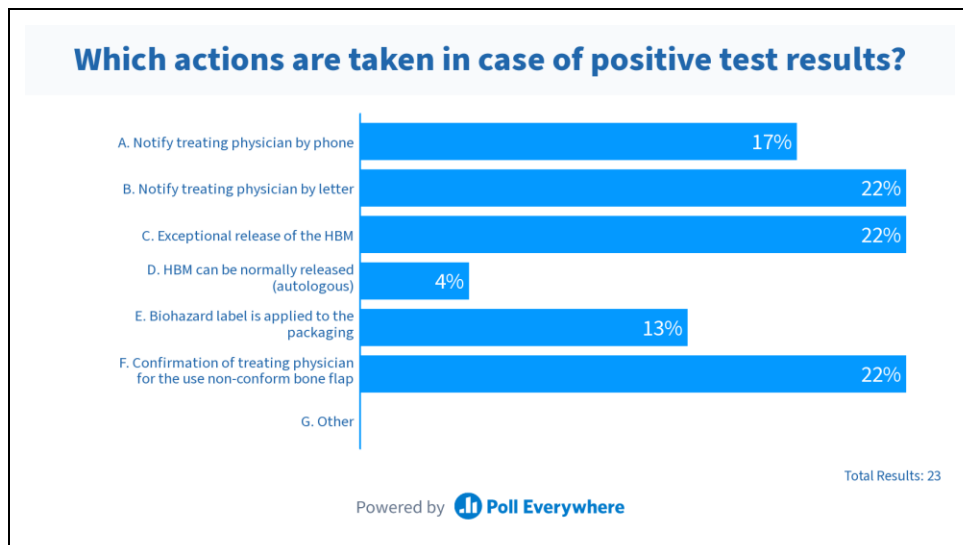
Dia 71

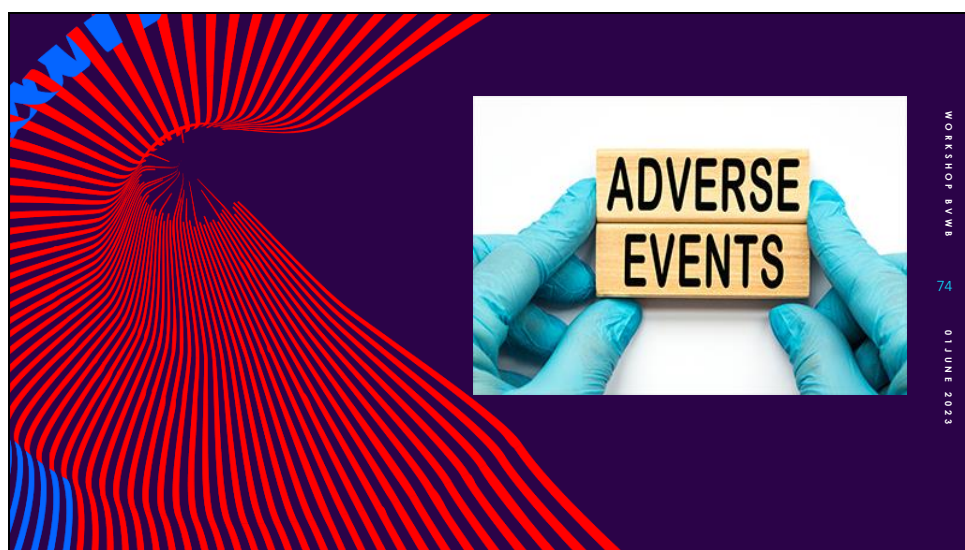


- One TE only stores the tissue for the neurosurgeon and does not take care of the serological results and release. According to law, it is a task for the TE?

Dia 72



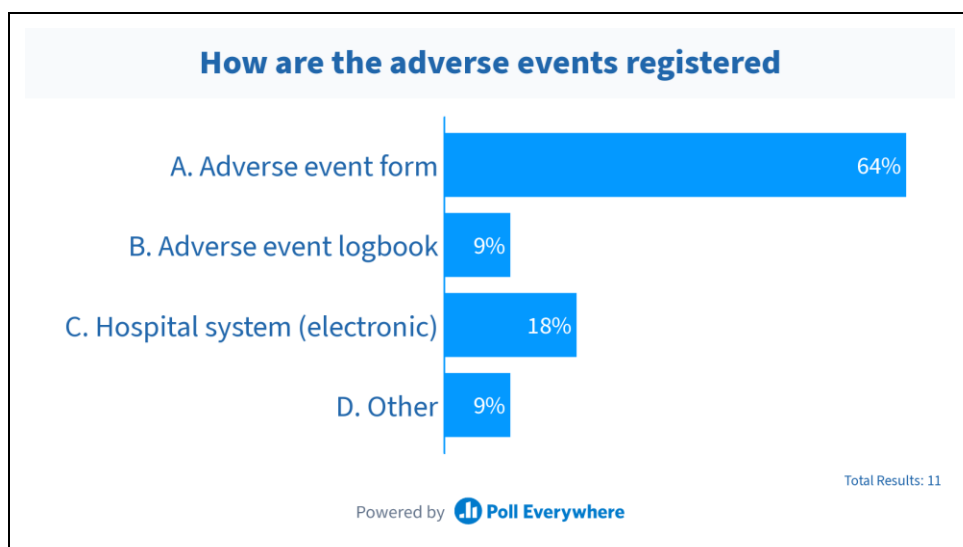




Dia 75

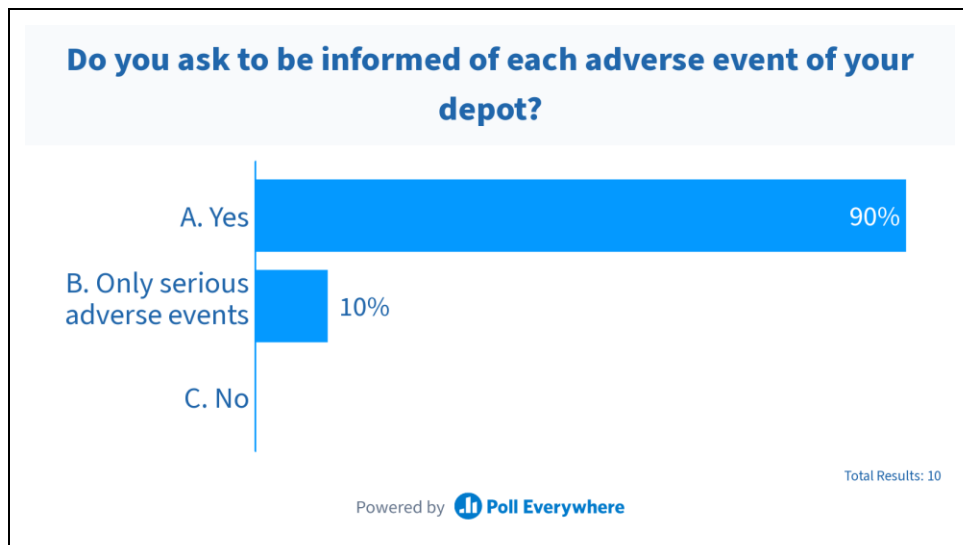


Dia 76

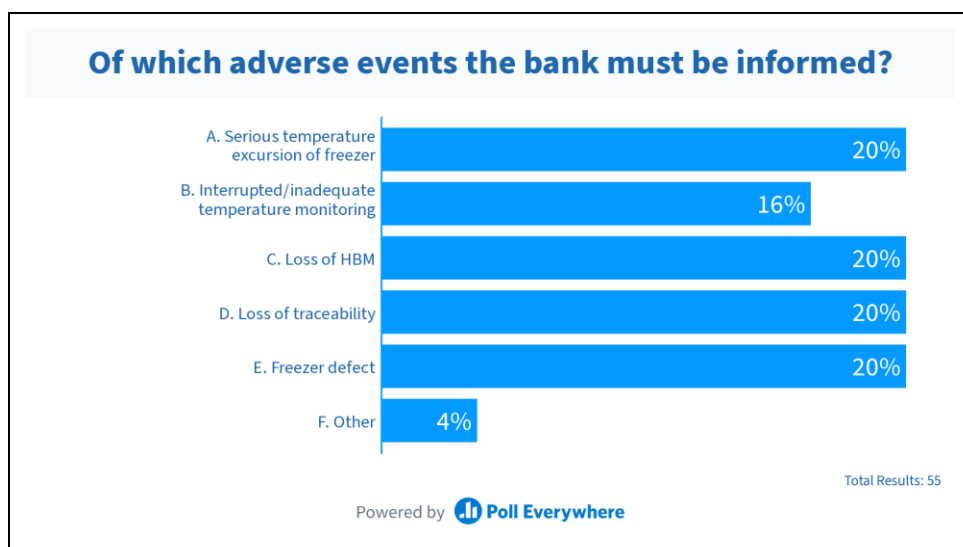


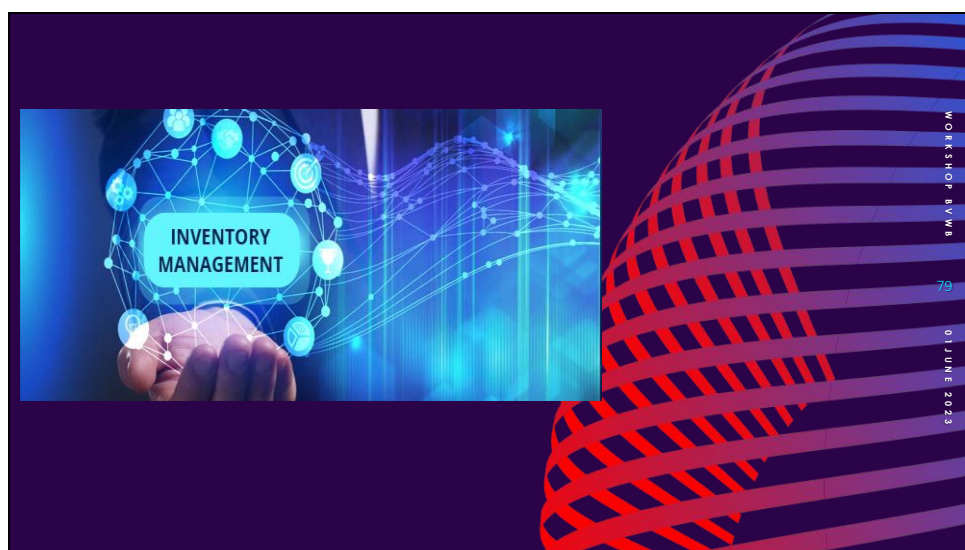
- Some depots have an adverse event/reaction log book or use non-conformity forms; others use the general electronic system of the hospital.

Dia 77

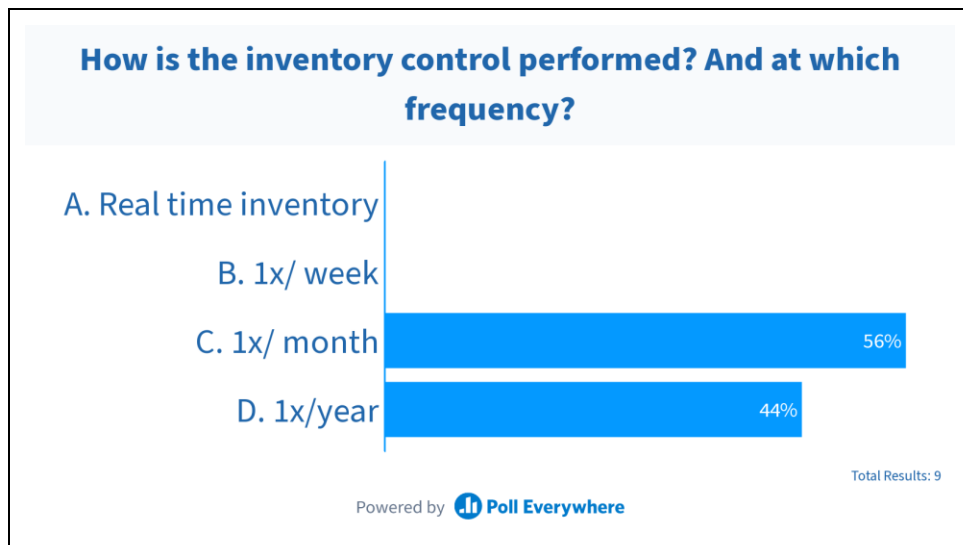


Dia 78

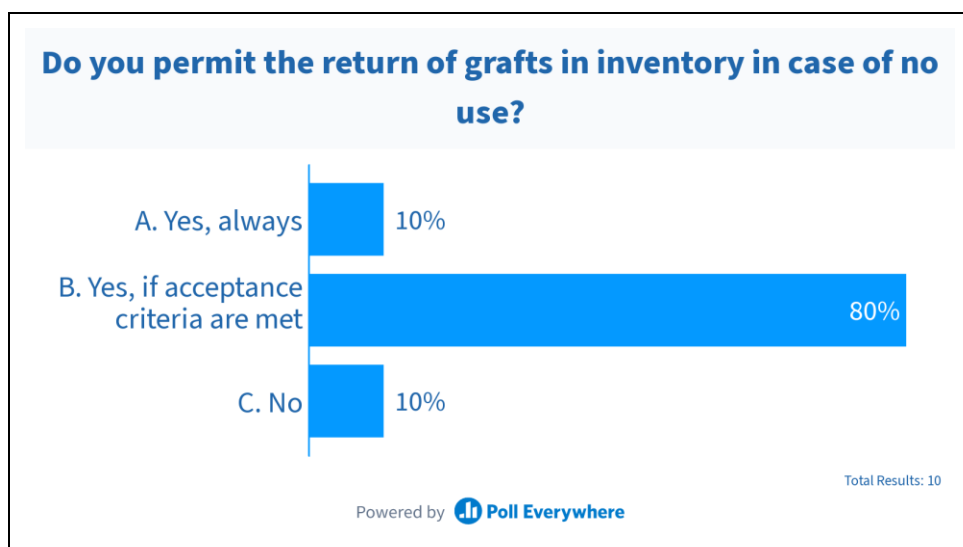




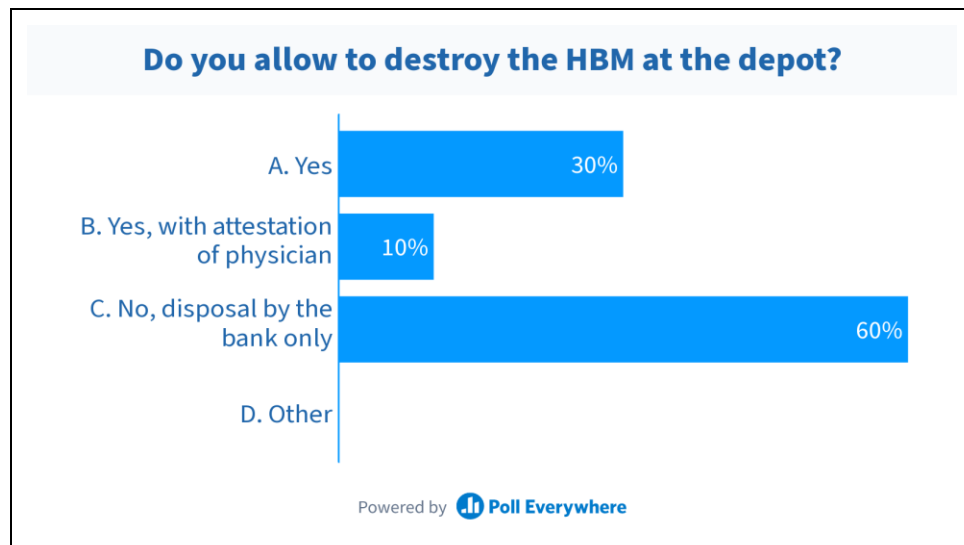
Dia 80



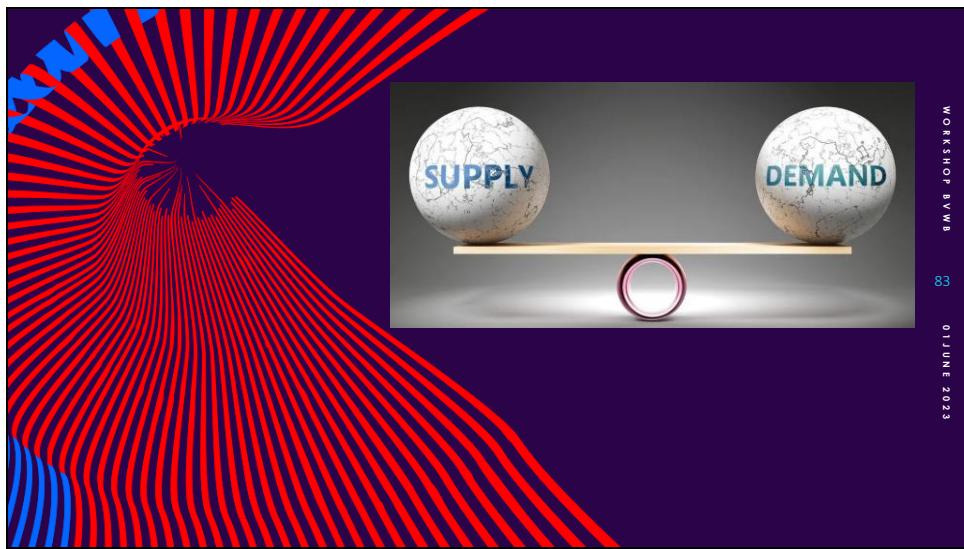
Dia 81



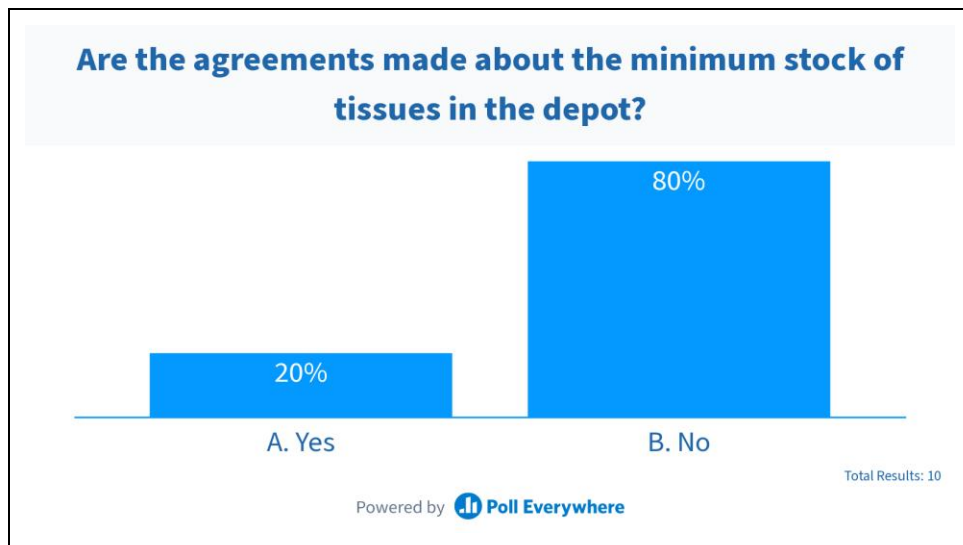
- Criteria:
 - o Less than 10 minutes out of the freezer (validation required) or use indicator to see if temperature was above -20°C and for how long (€)
 - o Packaging still sealed, documentation available



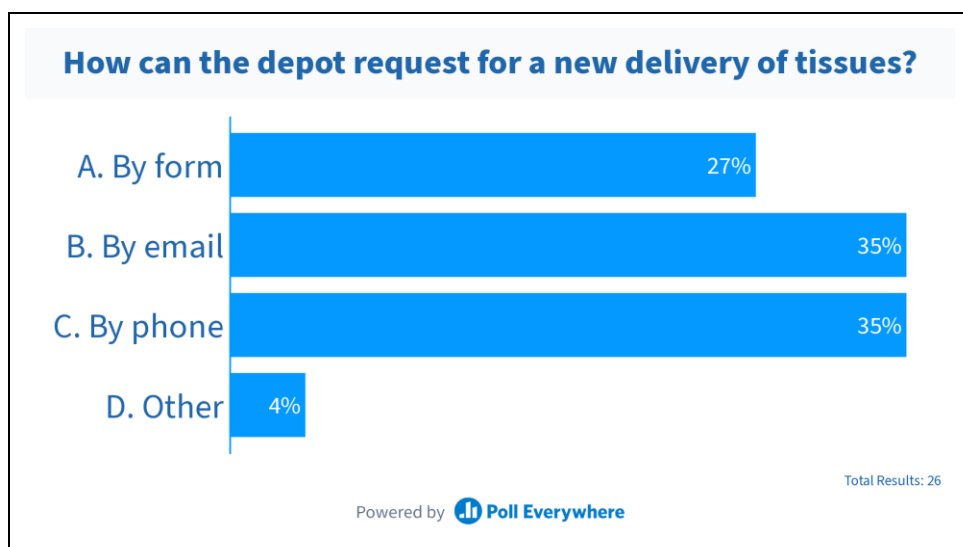
Dia 83



Dia 84

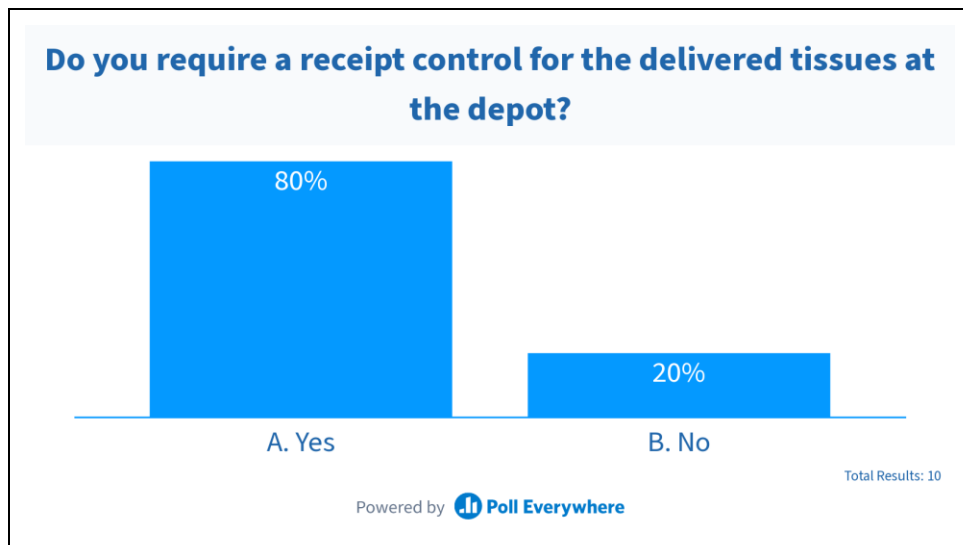


Dia 85

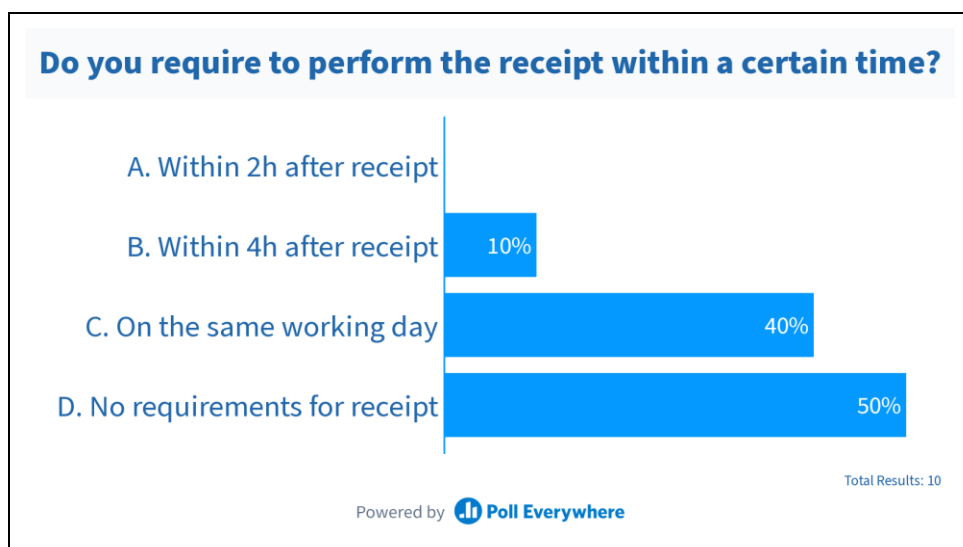


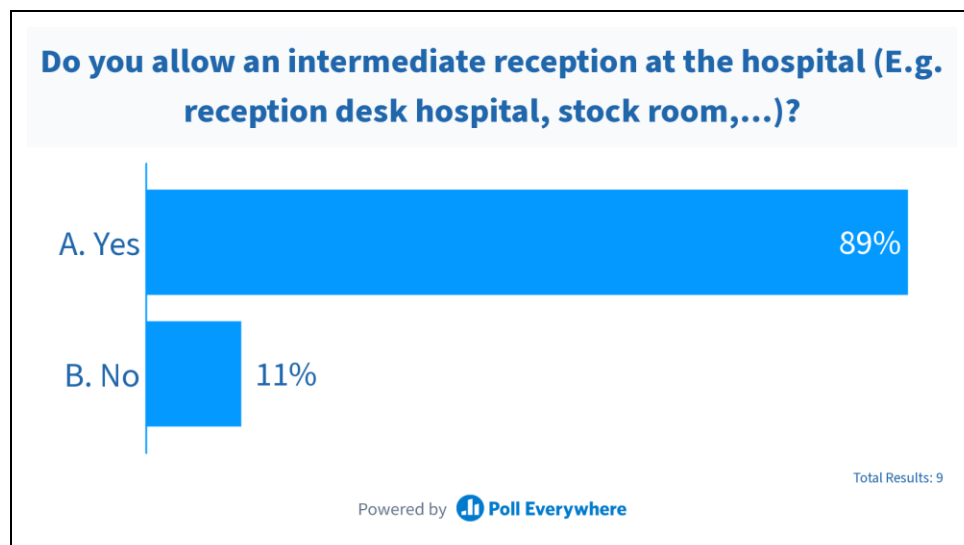
- Suggestion to use fixed delivery dates (genre "bofrost") => this optimizes the organization.

Dia 86



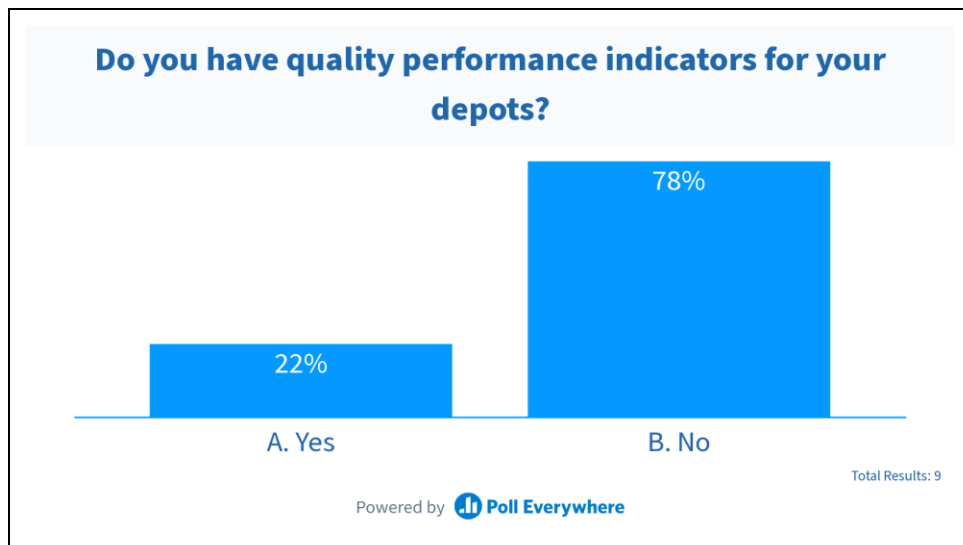
Dia 87





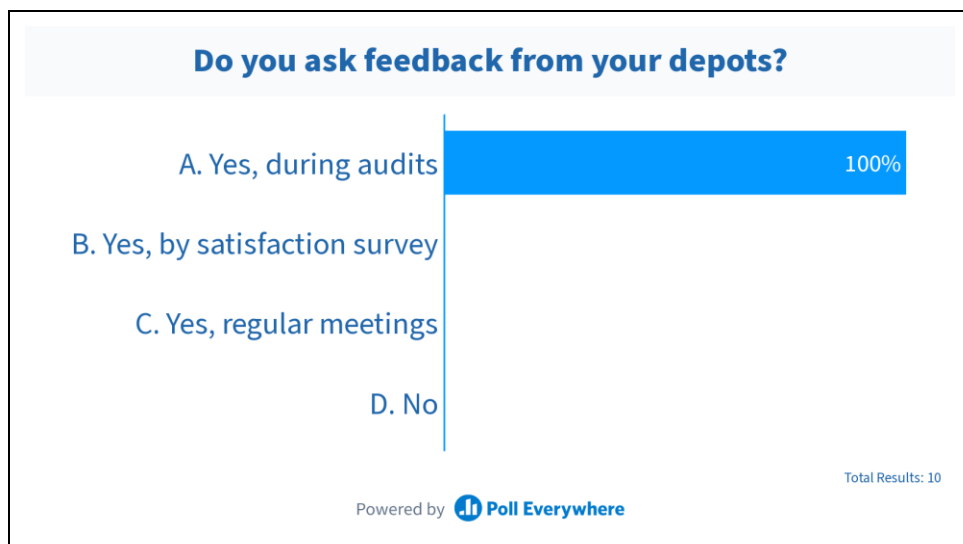


Dia 90



- Some examples of common QPIs were given: % discarded collected tissues / year / hospital; % microbiological positive results / year / hospital; number of discrepancies in inventory, number of non-conformances,...

Dia 91



- Remark: There is no clear follow up of the outcome for musculoskeletal tissues. However, the relevance is questioned for those cases where it concerns the replacement of a tissue by a graft.

Dia 92



How would you rate today's training?

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