

Amyloidosis center set-up checklist

This checklist provides a roadmap for healthcare professionals aiming to establish a new amyloidosis center in Europe or Japan. By following these steps and considerations, you can increase your chances of establishing a successful amyloidosis center to improve care for patients and expand the global center network.

This checklist is a starting point and intended for general guidance only – adapt it to your specific context and the unique healthcare environment in your region. It is essential to adhere to all relevant healthcare regulations and accreditation standards specific to your country when establishing an amyloidosis center.

Center development and infrastructure

- ☐ **Define center mission and vision:**
 - ☐ Clearly outline the center's purpose, target patient population, and approach to amyloidosis care (e.g., diagnosis, treatment, research).
- ☐ **Assemble a multidisciplinary team (MDT):**
 - ☐ Recruit key specialists from cardiology, neurology, hematology, and pathology.
 - ☐ Find specialists from other relevant fields (e.g., rheumatology, gastroenterology, ophthalmology, radiology, orthopedics) to ensure comprehensive care.
- ☐ **Secure appropriate facilities – locate a facility with dedicated space for:**
 - ☐ Consultation rooms for patient evaluation and management.
 - ☐ Diagnostic equipment areas (e.g., echocardiography machines, CMR machines, bone scintigraphy, biopsy suites, etc).
 - ☐ Pathology laboratories.
 - ☐ Administrative offices for staff and recordkeeping.
 - ☐ Treatment rooms for intravenous therapies and subcutaneous injections.
- ☐ **Develop a financial plan – outline start-up costs, including:**
 - ☐ Personnel salaries and benefits.
 - ☐ Equipment acquisition and maintenance.
 - ☐ Facility rental or ownership costs.
 - ☐ Operational expenses (e.g., IT, supplies).
- ☐ **Establish legal and regulatory compliance:**
 - ☐ Research and adhere to all relevant healthcare regulations and accreditation standards in your country (e.g., EU directives, Japanese Ministry of Health guidelines).
- ☐ **Invest in technology and infrastructure – secure necessary technology and IT systems for:**
 - ☐ Electronic health records (HIPAA-compliant if applicable).
 - ☐ Secure communication platforms for consultations and collaboration.
 - ☐ Laboratory equipment for initial testing (e.g., serum protein electrophoresis, immunohistochemistry, mass spectrometry, congo red staining).

Identify opportunities for funding and grant support

By exploring these avenues and crafting a strategic funding plan, you can increase your chances of securing the resources needed to establish a successful amyloidosis center:

- ☐ **Government health ministries**
 - ☐ **Research grants:** many countries offer research grants through their health ministries. Investigate programs dedicated to rare diseases or specific conditions like amyloidosis. These grants often support clinical trials, data collection, and research personnel salaries.
 - ☐ **Public health initiatives:** ministries might have programs focused on improving access to specialized care for underserved populations. Frame your amyloidosis center as a way to address a public healthcare gap and improve patient outcomes.
- ☐ **Disease networks and patient organizations**
 - ☐ **Patient advocacy groups:** connect with national or international amyloidosis patient advocacy groups. They may have resources or grant programs to support new centers for diseases like amyloidosis.
 - ☐ **National alliances or networks:** many countries have umbrella organizations for rare diseases. Explore their funding opportunities or inquire about grant proposals they might support.
- ☐ **Foundations and charities**
 - ☐ **Amyloidosis-specific foundations:** research foundations dedicated to amyloidosis research or specific types of amyloidosis might offer grants for establishing new centers.
 - ☐ **General health charities:** broader health charities may support initiatives that improve access to specialized care or advance medical knowledge. Highlight the potential impact of your amyloidosis center on patient lives and future treatment options.
- ☐ **Other strategies**
 - ☐ **Partnerships:** collaborate with existing hospitals or research institutions. They might be able to provide resources or cost-sharing opportunities to reduce your initial financial burden.
 - ☐ **Fee-for-service model:** develop a sustainable business plan that includes offering some services on a fee-for-service basis, while ensuring affordability and accessibility for amyloidosis patients. Establish a system for navigating patient insurance coverage.

Clinical care and patient services

- ☐ **Develop a referral process** for patients to reach your center effectively (e.g., through primary care physicians or other specialists). This should include a centralized intake system and the ability to care for patients via telemedicine if possible.
 - ☐ **Develop standardized diagnostic protocols** – establish a systematic approach for diagnosing amyloidosis, including:
 - ☐ Imaging modalities (e.g., echocardiography, scintigraphy, nuclear medicine, cardiac magnetic resonance) based on presenting symptoms.
 - ☐ Blood and urine tests.
 - ☐ Pulmonary function tests.
 - ☐ Biopsies needed (e.g., bone marrow, fat pad, minor salivary gland biopsy, heart biopsy, renal biopsy, skin biopsy for small fiber neuropathy).
 - ☐ General and neurological evaluation.
 - ☐ Genetic testing procedures and genetic counseling (if applicable for hereditary amyloidosis).
- NB: Check to see if there are any written standardized diagnostic and care protocols in your country.
- ☐ **Create treatment plans** – develop evidence-based treatment protocols tailored to specific types and severities of amyloidosis, considering:
 - ☐ Medications (e.g., chemotherapy for AL amyloidosis, disease-modifying therapies for ATTR amyloidosis).
 - ☐ Organ-specific supportive measures (e.g., heart failure management in cardiac amyloidosis).
 - ☐ Referral for liver or heart transplant when necessary.
 - ☐ **Consider offering genetic counseling services** to identify patients with hereditary amyloidosis and advise them and their families on genetic testing.
 - ☐ **Provide access to palliative care services**
 - ☐ **Develop model for effective multidisciplinary working:**
 - ☐ **Regular MDT meetings:** schedule frequent meetings (e.g., weekly or bi-weekly) for specialists from different disciplines to discuss complex cases.
 - ☐ **MDT consensus decision-making:** during meetings, promote collaborative discussion and shared decision-making on diagnosis, treatment plans, and patient management.
 - ☐ **MDT monitoring and care coordination:** establish protocols for ongoing communication and information sharing between team members to ensure coordinated care and track patient progress over time. Utilize the MDT meetings to review treatment response, address any complications, and adjust the treatment plan as needed. Care coordination can be provided by advanced practice providers (e.g., nurse practitioners and physician assistants).
 - ☐ **Integrate patient education and support** – establish programs to:
 - ☐ Educate patients about amyloidosis, treatment options, and self-management strategies.
 - ☐ Facilitate support groups for patients and families to connect and share experiences.
 - ☐ Provide or partner with social workers to assist with navigating financial aid, insurance, and other challenges.

Networking and capacity building

- ☐ **Collaborate with existing amyloidosis centers:** seek mentorship and share best practices with established amyloidosis centers in Europe or Japan, respectively.
- ☐ **Engage in research activities:** partner with research institutions to participate in clinical trials and contribute to advancements in amyloidosis treatment.
- ☐ **Develop educational outreach programs:** organize workshops or outreach events for primary care physicians and other specialists to raise awareness and improve early referrals.
- ☐ **Advocate for amyloidosis awareness:** partner with patient advocacy groups to raise public awareness of amyloidosis through educational campaigns.

Measuring success and quality of care

- ☐ **Implement quality assurance measures:** develop a system for monitoring the quality of care provided at your center. This might include:
 - ☐ Regular audits of medical records to ensure adherence to diagnostic and treatment protocols.
 - ☐ Performance indicator tracking to monitor patient outcomes, such as survival rates, response to treatment, and complication rates. This data can also be used to contribute to amyloidosis research. Examples of potential metrics include:
 - Time from request to appointment completed.
 - Time from symptom onset to definitive diagnosis.
 - Time from original request to initiation of amyloid-specific treatment.
 - ☐ Patient satisfaction surveys to gather feedback on the quality of care and patient experience.
- ☐ **Standardize data collection and reporting:** establish a system for collecting and storing patient data securely. Utilize standardized data collection tools to ensure consistency and facilitate outcome analysis.
- ☐ **Benchmarking:** regularly compare your center's performance metrics against national or international benchmarks for amyloidosis care. This allows you to identify areas for improvement and stay updated on best practices.
- ☐ **Continuous quality improvement:** foster a culture of continuous quality improvement within your center. Regularly review quality control data and use it to identify areas for improvement.