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Funding and Planning: What You Need to Know for Starting or Expanding a Home Hemodialysis Program

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**Implementing
Hemodialysis in the Home**
A Global Perspective

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International Society for Hemodialysis

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Abstract

Planning and funding a home hemodialysis (HD) program requires a well-organized effort and close collaboration between clinicians and administrators. This resource provides guidance on the processes that are involved, including: a thorough situational analysis of the dialysis landscape, emphasizing the opportunity for a home HD program; careful consideration of the clinical and operational characteristics of a proposed home HD program at your institution; the development of a compelling business case, highlighting the clinical and organizational benefits of a home HD program; and careful construction and evaluation of a request for proposal.

Introduction

Making the correct fiscal case for change is a crucial step in developing a home hemodialysis (HD) program. Smaller programs or pilot projects can often be started and managed within existing hospital HD infrastructure with costs being absorbed into existing funding. Once programs grow to beyond 5-10 patients; however, there is often requirement for separate and specialized home HD infrastructure and staffing. Figure 1 compares the size of home HD programs between Japan and Australia/New Zealand.^{1,2} In Japan, most home HD programs are small and located within hospital HD facilities.¹ In Australia/New Zealand, home HD programs are larger and, in most cases, enabled by specialized facilities and personnel.² Expanding a home HD program therefore requires substantial resources, and typically this requires a sound business case for financial investment.

Functionally, a proposal to start or expand a home HD program can be regarded as a 3-step process:

1. Development of an overarching clinical and strategic framework
2. Consolidation of these principles into a formal business case
3. Execution and handling of a request for proposal (RFP)

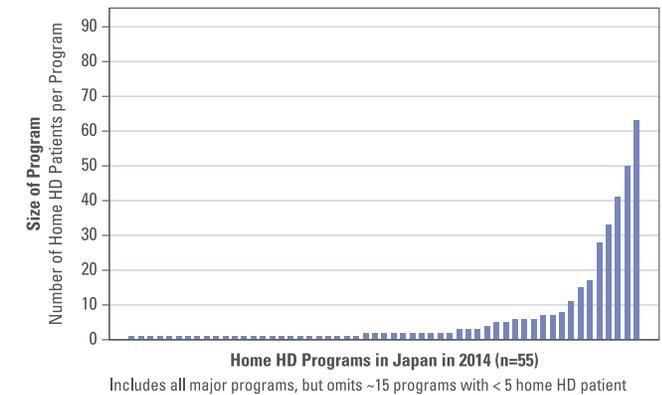
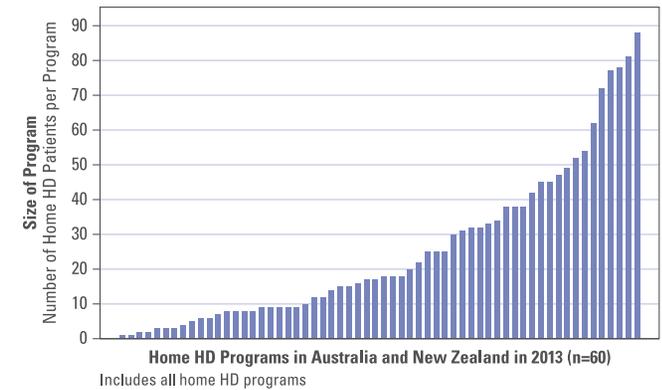


Figure 1. Size of Home HD Programs in Australia and New Zealand and Japan.^{1,2}

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It is vital that the framework and business case are credible and well supported: most providers and payers without experience of home HD programs perceive a high degree of clinical and financial risk in establishing a new home HD program, particularly when they are uncertain about the benefits to patients.³ For those responsible for developing the business case, choosing an overarching framework and deciding on suitable content can be daunting. In order not to be overwhelmed, we recommend that clinicians and administrators work together to accomplish these goals. The importance of this relationship cannot be overemphasized—an individual nephrologist may be able to start a pilot home HD project, but only a team effort will ultimately result in a sustainable and sizeable program.

The medical literature is the best starting point for evidence to support the project. Where it has been evaluated, home HD is less expensive than in-center (facility) HD and is associated with better survival and health-related quality of life.^{4,5} This has been demonstrated for both conventional short-hour, thrice-weekly HD, as well as frequent and/or extended-hour HD in the home setting.⁶ In 2010, the United Kingdom's (UK's) National Health Service (NHS) Purchasing and Supply Agency published an economic report of home HD, using assumptions based on the most likely UK scenario at the time. In that report, home HD dominated satellite HD with a cost saving of approximately £17,000 and a quality-adjusted-life-year (QALY) gain of 0.38 over a 10-year time horizon.⁷ Home HD also dominated hospital

HD, with similar cost saving and QALY gain. The greater cost of satellite and hospital HD was mainly attributed to a greater number of dialysis staff employed and patients' travel-related costs. Despite the high initial (front-loaded) costs of home HD due to patient setup and training, the payback period (relative to facility HD) is typically estimated to be relatively short at approximately 14 months.^{4,7-9} When considering these economic evaluations, one must be aware that most are biased *against* home HD, as these evaluations yield intentionally conservative estimates of cost-effectiveness (eg, no survival benefit is used in base case scenarios, despite multiple observational studies reporting this benefit).¹⁰

To navigate this process more easily, the following resources have been developed by a group of clinicians and administrators with first-hand experience in home HD and can be used in the development of business cases and RFPs.

- A set of questions for consideration, which will help inform the business case in the areas of capital, staffing, maintenance, and stakeholder consultation
- Guidance on how to write a business case for a home HD program
- Practice tips for dealing with RFPs

The questions in the next section should be considered in detail, before starting or expanding a home HD program, or writing a business case. For each set of questions, we have indicated

specific resources that are available to the reader for further information. The clinical and administrative leads of the project should be comfortable that the majority of these questions have been answered to their satisfaction. In most cases, however, there is no "correct" answer. Rather, we encourage readers to consider the options that are available to them, taking into account factors that are unique to their anticipated program structure and size, staffing sources, budget constraints, available equipment, local environment, and cultural practices. In some cases, we have clarified the question with additional considerations that are listed as bullet points.

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Questions to Consider Before Starting a Home HD Program or Writing a Business Case

Clinical Models of Care and Availability of Supporting Services

Q: What mix of home HD therapies will be offered?

- Identify the types of HD that the program will offer (nocturnal, short daily, conventional)
- Identify the frequency of HD that the program will offer (conventional 3 sessions/week, short daily 4-6 sessions/week, daily 7 sessions/week)
- Determine a targeted number of HD hours per week (eg, 12-15 hours/week, 15-20 hours/week, > 20 hours/week)
- Determine the maximum or minimum standards for the frequency and/or duration of therapy, set either by local clinical standards of care or pragmatic/costing constraints
 - » For example, the program might offer a minimum 12 hours of dialysis per week (clinical standard), but no more than 5 treatments per week (budget constraint)

Q: Why will these types of treatments be offered?

- Conceptualize the expected benefits for your program and your patients

Q: Is there good support for starting this program at your center?

- Consider the level of support among local nephrologists, nursing and multidisciplinary teams, management and hospital administration, as well as the level of support from regional or national authorities
 - » For example, in Ontario, Canada, the province pays for dialysis and is strongly supporting an initiative to increase the availability of all forms of home dialysis

Q: What is the capacity of facility HD programs?

- Determine if home HD is being considered because of capacity limitations in the hospital or satellite dialysis facilities
- Determine if there is sufficient capacity in either the proposed home HD unit or in other dialysis facilities to allow for fallback/respite care for home HD patients?

Stakeholders

It is important to clearly identify internal and external stakeholders in relation to a proposed home HD program. These specific people or groups are those who will be required to support the program, either through mitigating clinical and financial risks or through promoting and/or directly contributing to it.

Q: In your wider dialysis program, have you assessed patients' levels of awareness and interest in home HD?

- The most important stakeholder is the patient. During the planning process, there should be wide-ranging consultation with patients and advocacy groups. This should be done to ascertain the general level of interest in home HD, and also performed in a manner that promotes awareness and potential demand for the modality. This can be accomplished via a survey with an introduction containing a précis of clinical benefits, or through focus groups with patients and their families

Q: In your local region, are there initiatives or policies directed to increase the proportion of patients on home HD?

- Identify or create home HD patient recruitment pathways (see "Systems to Cultivate Suitable Patients for Home Dialysis" module)

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Q: What information is needed to approach the department of human services, government, or ministry payer for increased reimbursement and initial capital expenditure to fund a home HD program?

- Determine what their drivers are, and decide if it is possible to align with these entities to motivate home HD program development

Q: What factors will encourage administrators and clinical staff to become supportive and engaged?

- Those who are heavily invested in facility HD may see home dialysis programs as competition. It is important to have systems and strategies in place to promote your new home HD program to not only patients and families, but also to the members of your nephrology service as well

Q: How will home HD candidates be identified and made known to the home program?

- Many programs have found that it is difficult to move patients from facility to home HD. However, within most programs there are a small number of individual patients who will self-identify as candidates for home HD when informed of the availability of this modality, usually after a careful description of the advantages, disadvantages, expectations, etc. It is important to have systems and strategies in place to identify

such patients, and motivated and informed staff to approach patients with information about the modality and reasons why they should choose it. It is essential to promote home HD as an integral part of the shared decision-making process, when patients are discussing modality choice with predialysis educators and clinicians (see “Systems to Cultivate Suitable Patients for Home Dialysis” module)

- Home HD has been offered as a modality for patients who are failing peritoneal dialysis (PD) and want to maintain dialysis in the home setting. Programs that already offer PD should consider how to ensure that candidates for home HD are able to make a smooth and timely transition, when appropriate
- Patient selection criteria for home HD should be defined. Any proposal for starting or expanding a program should include estimates of growth and demand, which will in turn be determined by the number of recruits and the criteria used to select them (patient selection is discussed in detail in the “Patient Selection and Training for Home Hemodialysis” module). Any patient who is physically and cognitively able and motivated can perform home HD. In addition, there are many patients with complex combinations of comorbidities who have better outcomes with more frequent or longer HD treatments that are more easily administered in the home setting (refractory volume overload, difficult to control hypertension, right heart failure or uncontrolled ascites, persistent hyperphosphatemia, etc.). Clearly identify the types of patients within your service who could benefit medically from a survival and/or quality-of-life standpoint, and provide an estimated number of patients in the business case

Q: How will the home HD program integrate with local dialysis services?

- Determine if your home HD program will offer training and/or ongoing care to patients (and their care partner, if appropriate) for other regional dialysis services that do not have this option?

Q: For patients identified as candidates for home HD, what resources are required to ensure that such patients can have a smooth and optimal dialysis start?

- In particular, emphasis needs to be given to ensure that patients initiate HD as an outpatient with a permanent vascular access if possible
- Determine if staff (eg, a nurse navigator) and procedures are in place to help ensure that home HD patients are not lost to facility dialysis
 - » Even after patients are identified as candidates for home HD, many patients may still start HD urgently in a hospital setting¹¹

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Budget

A key component to a successful launch of a new home HD program is to ensure that the program is financially sustainable. It is accepted that home HD is a cost-effective alternative to conventional facility HD and an attractive option from a health system and societal perspective. However, these “global” cost savings may not help a local program that has day-to-day costs that are more than their incoming funding. For example, reductions in the costs of hospital admissions and medications may be attractive to the payer (eg, in the case of the Provincial Ministry of Health in Ontario, Canada), but these costs are usually not borne by the dialysis program, so they do not contribute to financial sustainability at the program level.

An important consideration is modality mix, in terms of extended-hours or frequent HD. Longer treatments have very low marginal costs per dialysis hour, as the only additional costs are for extra utilities (ie, power and water) and dialysate. More frequent treatments have higher marginal costs per dialysis hour due to the need for new connectology, tubing sets, and dialysis membranes.

Q: How does the dialysis equipment affect these costs?

- Systems that make extended use of dialyzers and tubing, for example, may reduce the marginal cost of adding extra treatments (see “Infrastructure, Water, and Machines in the Home” module)

Q: How is home HD funded in your local region (ie, paid by modality type, per week, or per treatment)?

- Funding per unit of time (eg, weekly or monthly) will make more frequent treatments less attractive from a budget perspective. This should not be a barrier when treatments are funded by modality type (for example, when nocturnal home HD is funded differently than conventional home HD) or when funded per treatment (the cost per treatment is similar for short and long home HD sessions)

Q: What are the anticipated costs relative to the funding level?

- Consider costs reimbursed to the dialysis provider and those borne by the dialysis program
- Determine if other programs in your region find that funding is at an appropriate level
 - » Anticipate that costs relative to funding are going to be high when the program is first initiated. Costs related to staff, space, overheads, etc., are often fixed (eg, clinical space must be allocated for regardless of whether there are a small or large number of patients), and incoming funding will be low due to the small number of initial patients. As the program grows over time, the ability to balance costs should improve, as the marginal costs of adding new patients are lower

- Programs should plan for how they will balance costs, because during the initial start-up period incoming funding will be low, and likely lower than costs

Q: What are the potential resource impacts on other hospital programs?

- Supporting a larger number of home HD patients over time will subsequently impact other hospital services, such as laboratory, interventional radiology, and inpatient services
 - » Patients undergoing home HD often require treatments and care in the hospital for a variety of reasons (eg, to address access problems, to treat acute illness, to provide respite care). Treatment space in either the home HD training area, hospital, or satellite HD facilities needs to be available to care for patients during times when they are ill or are unable to perform home treatments themselves

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Q: What should be done if the home HD program is running (or anticipated to run) a budgetary negative variance (ie, costs are higher than incoming funding)?

- Determine if payers provide “start-up” funds to cover the initial costs of starting the program
- Determine if the dialysis provider would be willing to lower costs in the initial phase of the program when patient numbers are low
- Determine if the home HD program can be administratively combined with programs running a budget with a positive variance (eg, combined with a PD program or a hospital/satellite HD program)

Home HD Training and Physical / Organizational Infrastructure

Q: Where will home HD training be performed, and where will the home HD hub be located?

- Possibilities include a purpose-built training and clinical support center; within an existing community health building, main hospital, or satellite HD facilities; or in another existing hospital space. For small programs, training can even be performed in the patient’s home. There will, however, always be a requirement for some clinic space to accommodate additional functions that support the entire patient journey (eg, clinical support, respite HD for patients). In smaller institutions, home HD and PD programs are co-located to allow for shared physical and human resources. For some, there is sufficient scale for each program to exist independently, and the infrastructure can be dedicated and orientated to purely home HD (see “The Home Hemodialysis Hub - Physical Infrastructure and Integrated Governance Structure” module)

Q: When will training occur?

- Home HD is often attractive to patients who are still employed. They may prefer to train at nights or on weekends

Capital Equipment

Capital equipment is one cost category where home HD is more expensive than facility HD. For facilities, an item such as a HD machine is typically shared among 6 patients, and a water treatment plant would supply water to all of the patients in a dialysis unit. In the home setting, each patient needs his or her own HD machine and water treatment equipment. In addition, the patient’s home may require moderate renovations to provide sufficient water, drainage, and electrical service to the room where the treatments will be performed (see “Infrastructure, Water, and Machines in the Home”). Additional items may be required for patient purchase, such as scales and blood pressure machines (see “**Patient Borne Costs**” section).

The major capital purchases for the home will include the HD machine and the water treatment system.

Q: How will this equipment be purchased or provided?

- Determine if the full amount will be required at the time of equipment acquisition, or verify if the vendor will allow for the capital costs to be incorporated into the ongoing supply costs, spreading the cost of purchasing the machines (lease model) over a period of time

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Q: How many HD and water treatment machines are needed for the program?

- Consider expected patient enrollment as well as extra equipment, as discussed in the “**HD Machine Maintenance and Delivery of Supplies**” section
- Consider the expected duty-cycle (life expectancy) of the home equipment. When the equipment is due for retirement, determine what funding will be available for replacing it?
 - » Some programs are required to pay an annual amortization amount on capital equipment. This cost should be incorporated into budget planning. Often, these funds go into the global hospital capital budget. Firm commitments need to be in place so that when the existing equipment reaches the end of its life cycle, these amortization funds are available to the renal unit for purchase of new home HD equipment
- Those starting a new home HD program should be aware of capital cost thresholds in their region. For example, in Ontario, Canada, some funders allow capital requests up to \$250,000 to be handled by the dialysis branch of the Ministry of Health. Beyond this level, the capital request must move to a higher level of governmental approval, where it may compete not only against other health-related applications, but against applications related to civic projects such as new roads, schools, etc. It may be beneficial to break a larger capital request into smaller requests dispersed over several years to stay within local capital threshold levels



Additional Resources

- Costs of starting and maintaining a home HD program:
 - » Komenda P, Copland M, Makwana J, Djurdjev O, Sood MM, Levin A. The cost of starting and maintaining a large home hemodialysis program. *Kidney Int.* 2010; 77:1039-1045.¹²
- Example of payer support for home HD:
 - » Nissenson AR, Moran J. A large dialysis provider committed to home modalities. *Am J Kidney Dis.* 2012; 59:739; author reply 739-740.¹³
- Example of a centralized home HD training model:
 - » Honkanen EO, Rauta VM. What happened in Finland to increase home hemodialysis? *Hemodial Int.* 2008; 12 Suppl 1:S11-15.¹⁴
- Example of home HD training in a Japanese HD facility:
 - » Tomita K. Practice of home hemodialysis in dialysis clinic. *Contrib Nephrol.* 2012; 177:143-150.¹⁵
- Home training support for patients in remote areas:
 - » Zacharias J, Komenda P, Olson J, Bourne A, Franklin D, Bernstein K. Home hemodialysis in the remote Canadian north: treatment in Manitoba fly-in communities. *Semin Dial.* 2011; 24:653-657.¹⁶

Staffing

Q: How will nursing and other dialysis staff be hired?

- Possibilities include hiring staff from the PD unit, hospital unit, satellite HD unit, other areas of the health service, or new hires
- In planning the number of required home HD training staff, it is important to consider how the home HD program will scale up from a small start-up to the full program

Q: How will technical support for home HD machines be provided?

- Possibilities include contracting with the dialysis HD machine provider or via hospital employees (biomedical engineers)

Q: What types of after-hours support will be provided to your home HD patients?

- Possibilities include 24/7 on-call renal nurses, dialysis machine technicians, hospital ward or emergency department staff, or none

Q: Will a nurse and/or technician home visiting service be provided?

- Most programs plan for periodic home visits by nurses and other health professionals. A number of issues that will impact program budgets and resources need to be considered:
 - » Determine how transportation will be provided for home visits (eg, taxi, hospital car, staff members' own vehicles, public transportation)
 - » For purposes of staff safety and security, many programs require at least 2 staff members perform a home visit. This off-site activity needs to be accounted for when planning staffing requirements

Q: How many staff and transportation vehicles are needed for home visits?

Q: How will new home HD staff be trained and developed? (See "Workforce Development and Models of Care" module)

HD Machine Maintenance and Delivery of Supplies

Q: What mechanism will be used for stock-take and delivery of supplies to patients' homes?

- Possibilities include an arrangement by the dialysis company or equipment vendor, or as an extension of hospital stores. Typically the dialysis company or equipment vendor provides this service

Q: Who will be in charge of ordering supplies?

- Typically it is the patient who tracks supply levels, orders when needed, and coordinates delivery times; however, this can lead to ordering an inappropriate number of supplies. Over-ordering may result in extra charges to the program for supplies that expire or go unused. Under-ordering can result in a patient not having essential items, necessitating urgent deliveries either by the vendor or the program

Q: In the case of using the dialysis vendor's systems, how will this be incorporated into the patient contract?

- Consider which party is liable for charges related to nonstandard deliveries (eg, special deliveries when a patient's dialysis prescription is changed, when a patient runs out of a particular item, or when a patient forgets to phone in their supply order)

- Similarly, determine who will be liable for extra delivery services for patients who require more frequent deliveries (eg, some patients need weekly deliveries of supplies due to highly restricted storage space in a small home)
- In the case of the home HD program providing this service, consideration should be given to the costs of stockpiling supplies and providing personnel and equipment to accept incoming orders from patients, and to coordinate the delivery service



Additional Resources

- Example of building a home HD unit from an existing PD unit:
 - » Borg DL, Keller JA, Faber MD. Adding home hemodialysis (HDD) to a peritoneal dialysis (PD) program. *Nephrol Nurs J.* 2007; 34:138.¹⁷
- Examples of resources required to start a new home HD program:
 - » Agar JW. Home hemodialysis in Australia and New Zealand: practical problems and solutions. *Hemodial Int.* 2008; 12 Suppl 1:S26-32.¹⁸
 - » Moran J, Kraus M. Starting a home hemodialysis program. *Semin Dial.* 2007; 20:35-39.¹⁹

Q: Waste management and disposal in the community: are there any local restrictions?

- If there are special disposal rules for used dialysis supplies, then the costs of recovering and disposing of waste items needs to be considered

Q: What are the arrangements for initial home HD power and water setup in patients' homes?

- Costs of setup will include modification of the home to provide adequate power and water for home HD. Some locales may require building permits prior to home modifications, which come at an additional cost
- Determine who will pay for this
 - » Some programs pay for all installation costs while others pay none of these costs. Some programs split the costs in some manner between the patient and program
 - » Determine if there will be an installation cost ceiling
- While some homes are modern and easily adapted for home HD, others require extensive retrofitting that can be costly. Determine at what point a home inspection will be performed
- Determine how contracts with plumbers, electricians, and other installation tradespeople will be managed
 - » One approach is to allocate a component of operational budgets for machine maintenance for each new patient setup

- » Determine who will be responsible for ensuring the quality of the work
- » It is important to remember that these modifications are being made in a patient's home, often in the bedroom. The installation of electrical and water services for a home HD system must not only meet technical and regulatory standards, but also be aesthetically pleasing. Patients will likely object to installations that are highly disruptive of the look of the home

Q: Who will pay for the home utilities including heating, power, and water?

- Possibilities include patients, local government, or patients with a subsidy from the government

Q: How will maintenance of the dialysis equipment be performed?

- Consider both routine and urgent maintenance (when equipment has failed). Determine if maintenance will be provided on-site in the patient's home, or will the equipment be swapped with a back-up machine
- If on-site maintenance is planned, determine if it will be provided by the equipment vendor or by the home HD program
 - » If provided by the vendor, then the terms of this service must be clear and incorporated into the contract

- » If provided by the program, then the program needs to provide (1) sufficient technical personnel, (2) a stockpile of parts, and (3) a method of transporting both equipment and technicians to the patient's home
- » Consider policies that limit the number of visits to the patient's home. Multiple visits to repair equipment can be very disruptive

- The program will need to maintain a pool of extra dialysis machines and water treatment systems to replace malfunctioning equipment that cannot be repaired in a timely manner
- If equipment is to be swapped for routine and urgent maintenance, several factors need to be considered
 - » Determine how equipment will be packaged and delivered. Consider both the replacement equipment being delivered to the patient, as well as the existing equipment being returned to the program
 - » Determine what types of delivery service guarantees will need to be in place (eg, timeliness of delivery, weekends and weekdays, care for fragile equipment)
- Consider how back-up equipment will be provided to those patients who live long distances from the dialysis program

Q: Who will provide periodic water monitoring, and what are the costs of this ongoing monitoring?

- It is important that the medical and administrative leads be familiar with local water quality regulations for the production of dialysate. These regulations will specify the standards for water quality, as well as the frequency and type of monitoring required (see “Infrastructure, Water, and Machines in the Home”)
- A clear delineation of responsibility for water quality is required. Typically, this rests with the medical director of the program, even when water testing is performed by external agencies

Q: How will maintenance of the water system be performed?

- Examples include swapping of carbon tanks and replacement of reverse osmosis (RO) filters
- Programs can combine staff visits with other home-based activities (eg, routine maintenance, water sampling)

Patient-Specific Costs

In a home HD program, some cost categories are moved from the program to the patient, which can potentially offset the benefits of home HD for the patient through avoiding other costs related to, for example, transport and parking. For example, home HD is associated with an increased demand for power and water, which are often paid for by the patient. Consideration should be given to the costs that may be borne by the patient and how these would be handled if the patient did not have sufficient resources to pay for them. It is important to be clear from the start who bears the financial responsibility for what costs, if necessary, by legal agreement.

Q: Who will pay for any renovations to the home required for the patient to initiate home HD?

- See “Checklist for Costs Related to Infrastructure for HD in the Home” in the Appendix

Q: Many rented or leased homes require that any dialysis-related alterations made to the home will be removed and the home restored to predialysis condition when the patient moves.

- Determine who will cover these costs

Q: If the program is covering costs related to home renovations, is there any limit to the number of times a patient can change residence?

Q: Who will pay for assorted single-time purchases such as scales, blood pressure machines, tables to hold equipment and supplies, recliner chairs, and leak detectors, if appropriate?

Q: How will the increased cost of power and water be handled?



Additional Resources

- Published examples of the costs of a home HD program:
 - » McFarlane P, Komenda P. Economic considerations in frequent home hemodialysis. *Semin Dial.* 2011; 24:678-683.²⁰
 - » Komenda P, Copland M, Makwana J, Djurdjev O, Sood MM, Levin A. The cost of starting and maintaining a large home hemodialysis program. *Kidney Int.* 2010; 77:1039-1045.¹²

Writing a Business Case for a Home HD Program

The next step in establishing a home HD program is to secure funding for capital and operational expenses and initiate the procurement of the necessary goods and services. To do so, most private and public payers require a business case: a document designed to justify expenditure of money and effort in order to make a decision on funding.

A compelling business case is a well-structured and logical document. It captures the expected clinical benefits of developing a viable home HD program for the patient, identifies the required resources, defines models of care, and determines the relative priority of the program in relation to competing initiatives.²¹ For the payer, the business case helps reassure that:

1. The program is a high-value opportunity with measurable and accountable clinical benefits
2. The nephrology service can deliver the purported benefits
3. Due consideration has been given to complex interdependencies with other services such as surgery, radiology, and information technology; and
4. Quality, patient safety, and incident management aspects of the program have been considered and incorporated

Occasionally, there will be payer templates available to use in preparing business cases; these should be followed strictly. More often, business cases are formal but unscripted, and should contain the key elements listed in Table 1.

Table 1. Key Requirements of a Business Case

Section	Key Requirements
Table of Contents	Display organization of the document and page numbers
Glossary	Define key terms
Executive Briefing or Summary	Convey to the audience what they can expect in the document. This section is an opportunity to have an immediate impact by presenting a succinct and compelling story around home HD
Introduction or Background	State the clinical need for home HD, include an opportunity statement (ie, the potential opportunities this service could provide), and establish a sense of urgency for the solution
Service Objectives and Critical Success Factors	Clearly explain how the home HD project outlined in the business case is connected to the strategic goals of the dialysis service, hospital, or provider
Approach or Methodology	Convey a deep understanding of the current clinical and financial landscapes using data and analyses—this is a crucial component of the business plan. If the payers do not understand or concur with the assessments in the business case, they will not be convinced enough to agree to its final recommendations around home HD
Overall Scenario Analysis or Justification	Provide high-level descriptions of the service options, tell how they fit within the existing organization, and note the key differences between service offerings so that the reader can quickly compare options. The financial analysis must answer the following key question: “Do the proposed options result in cost savings and/or avoidance of cost over an acceptable timeframe to the payer, or provide additional clinical effectiveness at an acceptable cost?”
Linkages and Stakeholder Summary	Identify any additional resources that may be needed, including the larger team required to make implementation a success
Implementation	Lay out a high-level plan for implementing the home HD program
Risks and Mitigation	Highlight the key risks to successful implementation

Glossary

- Provide a list of key terms used in the business case that may be unfamiliar to the payer (see Appendix)

Executive Briefing or Summary

- This should be succinct, and at most 1 to 2 pages long. The Briefing/Summary might start with foundational statements highlighting the limitations of facility HD (negative impact on clinical and patient-centered outcomes, high healthcare costs, etc.) and the benefits of home HD (clinical and patient-centered benefits, affordability)
- The Briefing/Summary should then:
 - » Summarize the clinical and financial data used for synthesis of recommendations
 - » Highlight, if appropriate, any unmet clinical need and the current difficulties with dialysis service provision (unsustainable growth in patient numbers, inadequate facility HD staff and infrastructure, unsustainable healthcare costs, etc.)
 - » Summarize recommendations contained in the business case
 - » State the recommended decision to be made by payers

Introduction or Background

- This section should contain the clinical and financial case for the home HD program relative to other competing options. This is an important section, because there is often a high degree of uncertainty about the possibility of financing home HD with payers. It is necessary, therefore, to highlight the clinical evidence supporting home HD to ensure a strong negotiating position with payers
- Provide necessary background for the reader by starting with a **general description** of conventional and frequent or extended-hour home HD, referencing national or international service trends around home HD use, and recommendations from local policies or clinical practice guidelines around optimal modality mix for services, or optimal modality selection for particular patient groups²²
- Next, provide a subsection outlining the **expected benefits of home HD** compared with in-center (facility) HD.²³ The business case needs to include clinical benefits of frequent and/or extended-hour modalities, because the establishment of a home HD program offers this technique to everyone, whether or not they choose to use it. The key benefits are as follows:
 - » Patient
 - Improved patient satisfaction and independence/empowerment²⁴⁻²⁶
 - Improved quality of life^{4,5}

- Fewer dietary and fluid restrictions^{27,28}
- Added convenience²⁹
- Reduced impact on family life⁴
- Improved maintenance of social functioning⁴
- Clinical benefits to the patient
 - › Reduced associated mortality risk compared with PD and other HD modalities^{10,30-33}
 - › Regression of left ventricular mass³⁴⁻³⁵
 - › Improved blood pressure control³⁶
 - › Improved serum phosphate control³⁷
 - › Greater chance of successful pregnancy^{38,39}
 - › Increased urea clearance^{25,40}

» Healthcare costs

- Reduced travel costs for patients⁴¹
- Reduced medication costs due to improved blood pressure control and improved mineral metabolism^{34,35,40}
- Reduced dialysis staffing costs⁴¹
- Reduced costs from constrained facility HD infrastructure

- A **situational analysis** should be included that defines renal replacement therapy within the current dialysis service, provides growth projections in terms of dialysis populations and modality mix, provides geographical mapping, and offers a summary of the strategic direction and optimal clinical model for dialysis services within the organization. Ideally, this includes a patient segmentation exercise to determine the expected demand for home HD in the service. It is vital that the modeled demand for home HD patients is realistically aligned to the potential within the current patient population
- The situational analysis should also provide a **gap analysis**. This analysis is a comparison between the current situation with respect to delivery of home HD vs the optimal or future situation
- It is vital that the business case considers a **range of options** as alternatives to home HD, as well as the option of doing nothing (that is, maintaining a similar patient distribution among the different modalities). It often helps to have a patient dialysis modality profile such as the one offered in Table 2. This is not a guide defining those who can perform home HD or derive benefit from this therapy; instead, it builds a portrait of potential patients for those in clinical governance and executive leadership groups who may have very little experience in dealing with renal patients in general and dialysis in particular. In our experience, this has been a very useful inclusion in business cases

Table 2. Patient Dialysis Modality Profiles

Patient Dialysis Modality	Key Characteristic	Location	Examples of <i>Typical</i> Demographic (needs to be localized to each service)	Specialist Clinical Support
Dependent stable +/- medically unstable	Model of care is provided by specialist clinical support	In-center or hospital HD facility	<ul style="list-style-type: none"> • Person aged > 75 years • Person with ≥ 3 comorbidities • Requires social or functional assistance at home • Not working 	<ul style="list-style-type: none"> • Access to acute medical services • High nursing input (eg, dressings) • Requires specialist HCP review approximately weekly • Frequent hospital admissions
Self-care	Patients who are expected to perform a portion of their dialysis treatment	Satellite HD facility	<ul style="list-style-type: none"> • Person aged > 60 years • Person with 1-4 comorbidities • May require some social or functional assistance at home • < 50% working or full-time house duties 	<ul style="list-style-type: none"> • Low nursing input • Specialist HCP review approximately monthly
Home HD	Patients who are expected to perform their dialysis procedure independently after training	Home setting	<ul style="list-style-type: none"> • Person aged < 70 years • Person with 1-4 comorbidities • Independent at home • > 50% working or full-time house duties 	<ul style="list-style-type: none"> • Low nursing input • Monthly laboratory review • Self-manages dialysis at home • Primary contact is primary nurse • Specialist HCP review ≤ monthly
Peritoneal dialysis	Patients who are expected to perform their dialysis procedure independently after training	Home Setting	<ul style="list-style-type: none"> • Person aged < 70 years • Person with 1-4 comorbidities • May require some social or functional assistance at home • < 50% working or full-time house duties 	<ul style="list-style-type: none"> • Low nursing input • Monthly laboratory review • Self-manages dialysis at home • Primary contact is primary nurse • Specialist HCP review ≤ monthly

HCP = healthcare provider.

Service Objectives and Critical Success Factors

- This section should contain definitions for service objectives, which are the anticipated benefits of starting or expanding the home HD program. These objectives can be used to compare the option of home HD with other dialysis modalities. Some examples of commonly used service objectives are provided in Table 3
- The *critical success factors* in Table 4 can be used to score the various options

Table 3. Commonly Used Service Objectives in Business Cases for Home HD

Service Objectives	Definition	Exemplary Considerations
Clinical Results	Optimizing clinical outcomes of the service	Do the proposed solutions improve patient outcomes (eg, mortality and health-related quality of life), increase patient safety, or decreased hospitalization?
Access to Optimal Care	Bringing the clinical and patient benefits of home HD to the service in an equitable manner	Do the proposed solutions increase the proportion of patients treated with home HD, especially frequent or extended-hours HD, including those in geographically remote areas?
Meeting Dialysis Demand	Ensuring sufficient service dialysis capacity to enable treatment to new patients	Do the proposed solutions provide adequate capacity for growth in patient numbers over the period of the proposal?
Constraining Facility HD Capacity	Providing an alternative to facility HD capacity investment, thereby using this resource more efficiently for the more dependent patient group that needs it most	Do the proposed solutions avoid significant investment in infrastructure through decreased relative utilization of facility HD, or improve access to care through community-based health service delivery?
Safety	Providing a clinically safe and sustainable service	Are the proposed solutions likely to result in excess patient mortality, hospitalization, or emergency care consultations?

Table 4. Commonly Used Service Objectives for Determining Critical Success Factors in Business Cases for Home HD

Objectives	Scoring
Service Objectives	The extent to which objectives of clinical care are realized by the proposed option
Strategic Fit	The extent to which the proposed solution meets the strategic objectives of the healthcare organization, as well as regional and national objectives
Achievability	The capacity and capability of the service to implement the proposed solution within required timelines
Scalability	The extent to which the proposed solution can be expanded or contracted to meet demand
Affordability	The ability of the payer to afford the capital and operating costs of the proposed solution

Approach or Methodology

- This section describes the research methods and sources of data used in the business case. Sufficient information around the approach and methodology used in this exercise will convince payers of the credibility and validity of the business case. For instance, if the scenario analysis uses prevalence and modeled growth data, then the source of those data and the methods for modelling should be described. If the analysis uses new data on qualitative issues that have been collected as part of business case, the method should also be described (focus groups, ethnography, stakeholder interviews, surveys)

Overall Scenario Analysis or Justification

- This section contains a description of the home HD program option and each alternative option, along with financial analyses for each. For payers, home HD is perceived to have high initial setup and training costs with an uncertain financial payback period. Therefore, it is essential to have a high degree of clarity around the implementation and cost models for home HD. Ambiguity may increase the likelihood that the payer will fail to consider new alternatives and default to facility HD
- Evidence should be provided for each option in an *overall scenario analysis*. In this analysis, there is a detailed description of each option within the business case, justifications for models of care, and robust financial evaluations. Each option should be assessed against the clinical objectives and scored using the critical success factors illustrated in Table 5
- A key part of the Overall Scenario Analysis section is *financial analysis*, which includes the costs and risks of inactivity. Although this is important, it is often impossible to precisely quantify costs until a preferred option is identified from the RFP. As such, costing is often based on a number of assumptions around the costs and outcomes of each option. The general method to perform a financial evaluation is as follows:
 - » Apply all calculations over an agreed timeframe (eg, 5 years)

- » Determine expected growth rate of the dialysis population
- » Create scenarios based on different patient distributions in the future across different modalities, considering local nuances such as self-care and satellite HD, because these may significantly alter estimates of cost and reimbursement. When modelling home HD, take into account dropouts to facility HD and transplantation. Depending on the setting, dropout from home HD may be on the order of 20% per year, mostly due to transplantation and illness resulting in a transfer to facility HD
- » Perform the cost calculation on a per-year basis for each modality. Three considerations should be made:
 1. It is important to break down the patient distribution to frequency per modality (eg, 4 sessions per week home HD), as the treatment schedule also affects the cost
 2. Where possible, a full-cost accounting approach should be used, which takes into account all direct and indirect costs
 3. An increase in home HD patients in the program leads to more home HD machines proportionally than a corresponding increase for facility HD, and, therefore, different capital costs

- » Costs categories might include those related to:
 - Staff (including departmental and administration overheads, direct and indirect nursing care, technical support)
 - Facilities (including utilities and equipment)
 - Dialysis machinery, consumables, and technical considerations (machine purchase or lease, technical support, water management and treatment, waste management)
 - Additional miscellaneous costs (medication,

transportation, training costs for home HD, utilities and home equipment for home HD, etc.)

- » In dialysis services that are block-funded (ie, one funding source to be dispersed as the clinic sees appropriate), these cost calculations will suffice. For those that are revenue or activity-base funded, the operational margin per modality should be calculated to identify the difference between the reimbursement level and the costs for a specific modality

Table 5. Commonly Used Service Objectives and Sample Scoring Matrix for a Home HD Business Case

Dialysis Service Options	Critical Success Factor (score)				
	Service Objectives (1)	Strategic Fit (2)	Achievability (3)	Scalability (4)	Affordability (5)
Home HD	✓	✓	✓	✓ or ✗ ?	✓
Option B	✗	✓	✓	✗	✗
Option C ...n

Linkages and Stakeholder Summary

- Detail in this section any organizational changes expected to allow the home HD program to be implemented, and acknowledge the independent requirements from other clinical and logistic services. Consider including the following issues:
 - » New infrastructure and space requirements (eg, offices, space for patient training, patient waiting area, respite care)
 - » Modifications to existing infrastructure and spaces (eg, construction, plumbing, and electrical work)
 - » Clinical process changes and modified patient pathways
 - » Workforce development and new roles and responsibilities for the home HD program (new nursing and medical supervision requirements, new administrative roles)
 - » Impact, if any, of the home HD program on surgery and radiology
 - » Information technology (IT) system requirements
- Do not forget to identify or quantify any improvements in resource utilization arising from the home HD program (ie, freed capacity from constrained growth for facility HD)
- In this section, it is also useful to provide a list of the stakeholders who have been consulted in the development in the business case. This helps reassure the payer that complex requirements and relationships have been considered, and there is a low likelihood of unforeseen challenges that might derail or delay the implementation of the business case

Implementation

- This section defines timelines for the initiation of the first patient in the home HD program and serves as a checklist of milestones that should be achieved along the way

Risks and Mitigation

- Explain what might not go as planned and categorize the likelihood of the risks as high, moderate, or low. If there do not appear to be any foreseeable risks, it is important to ensure that the audience realizes that this is a considered position, and that this issues have been thought through
- The primary risks to be considered are to costs and schedule. For example:
 - » What if the costs or availability of home HD machinery changes?
 - » What if the project manager or team changes or leaves? What if the home HD champion or clinical lead changes or leaves?
 - » What if clinicians or patients struggle to adopt or adapt to the new home HD program?
 - » What if the home HD equipment or infrastructure does not perform as expected (eg, quality, performance)?
 - » What if vendors do not deliver on time?
 - » What if the cost of raw materials increases?
- In this section, propose strategies to mitigate these risks and identify any opportunities that might arise

Dealing with RFPs

When a large contract or capital proposal is being offered to vendors, most private and public payers require that a RFP or request for tender (RFT) process be followed. The RFP process is usually highly scripted, with many rules and regulations. In the case of publicly funded systems, the RFP process may be codified in law. In all cases, the RFP process *must* strictly adhere to the local rules and guidelines to protect the program from a variety of liabilities. As a result, it is in the interest of those starting a new home HD program to become familiar with their local RFP process.

Before embarking on an RFP for home HD equipment and service, it is important to become familiar with the strengths and weaknesses of various vendors. Once an RFP is open for tender, it usually cannot be altered. The RFP process is not the time to learn about what vendors are able to offer—this should be done before construction of the RFP. The RFP is best written by a multidisciplinary home HD program team, including an experienced dialysis nurse and technician. This team will research the following topics and consider the costs, where applicable.

The HD Machine

- Research and choose the best HD machines available for home use. From the short list of selected machines, the team will determine the best machine option by assessing the following questions:
 - » Is the machine appropriate for the home setting? Consider the size, noise level, ease of use, screens that can be accessed from the supine position for those patients undergoing nocturnal treatment
 - » Will it be easy to train patients on this system? For example, does the machine take the patient step by step through the procedures for starting and finishing dialysis?
 - » How long does it take to set up the machine and to disconnect from a treatment? How many steps are required to perform these tasks?
 - » Is the machine easy to maintain and repair?
 - » Is it flexible enough to provide a variety of forms of dialysis? For example, quotidian nocturnal HD with long treatment times using low blood and dialysate flows, and conventional HD with fast pump speeds?
 - » What safety features are provided (eg, blood leak/needle disconnect sensors, blood pressure monitors)?
 - » What language requirements are there in your home HD program, and does, or can, the dialysis machine support specific language requirements?

- What range of dialysate concentrates is available, and do these dialysates meet the various needs of your patients (eg, nocturnal HD often requires a higher calcium dialysate; patients performing extra hours of HD per week may not need a very high bicarbonate concentration or very low dialysate potassium)?
- » How easy is it to “spike” the dialysate to customize the composition (eg, adding calcium or phosphate to the dialysate)?
- » Home HD equipment is often located in less than ideal environments and may not be treated gently at all times. How robust is the equipment?
- » What happens if the power fails during treatment? Can the machine recover from short power failures? What are the procedures for returning the blood after a power failure?
- » How quickly can the equipment be ready to provide the next treatment?
- » What are ongoing maintenance requirements for the machine, and how difficult will maintenance be for the patient to contend with?
- » Modern HD machines offer a wide range of additional features, some of which may not be of particular value in the home setting; however, they may still be desired. The program team needs to decide if they value features such as online hematocrit monitoring, sodium profiling, etc., before investing in a machine that includes these features

The Water Treatment Equipment

- Is ultrapure dialysate desired, and if so, can the water system provide that?
- The RO unit is often the loudest part of the system. What is the volume level while operating the water treatment system?
- How can leaks be detected and how will leak status be communicated to the patient?
- Is the water treatment system integrated with the dialysis machine? Will it be provided by the same vendor?
- How easy is the machine to maintain and to clean?
- The patient will typically perform the routine cleaning. Will they also be doing tasks such as replacing RO cartridges?
- Will the vendor provide maintenance and/or supply delivery services? (See “Ongoing Maintenance and Supply Delivery” section)
- Will the vendor provide after-hours support, service, or maintenance? (See “**HD Machine Maintenance and Delivery of Supplies**” section.)
- Does the vendor already provide these services in your region? What is their reputation for reliability? Speaking to senior technicians from other home HD programs may be useful

Information Technology

- What IT systems will be requested from the vendor? These can range from simple systems that interface with the HD machines to full electronic medical records
- What are the purchase costs for the IT systems? Are there ongoing charges for the use of these systems?
- How will home equipment and patients interface with these systems? What equipment will be needed in the home for this? What type of IT connection will be required (eg, high-speed Internet)? Who will pay for the costs of connection?

Full-Service Provision Options

- Has due consideration been given for outsourcing of the home HD service, in terms of partnership with a large dialysis organization (LDO)? This is an emerging clinical and business model and is an arguably easier way to start a home HD program, where clinical and financial risks may be mitigated by an experienced LDO

Once the home HD program team has become familiar with the offerings of the various vendors active in their region, the RFP can then be constructed. It is crucial that the program team be clear about which features and services they expect from the vendor and their equipment. The program team should construct a “wish list” of desired features and rank them in terms of importance. Some features are critical and a vendor will be eliminated if they cannot deliver this feature. Others will be desirable, but will not necessarily be deal breakers if they are absent. Proper construction of the “wish list” is important because most RFP processes require not only a list of desired features, but the weighting applied to each of these features. The vendors will be asked to submit a list of services and equipment that will be provided, and a list of charges. The program team should understand its budgetary limitations before constructing the RFP and consider what weight will be applied to the budget component of the RFP.

It is extremely important that the RFP be constructed properly. The RFP should be written in a manner that ensures that the program team is able to select a vendor that will meet not only all of their needs but also the program's budgetary requirements as well.

A vague and poorly written RFP may lead to selection of an inappropriate vendor.

Because the RFP process is highly regulated, the program team involved in creating the RFP should understand the local rules governing that process. For example, once the RFP is completed and open for vendors to review, changes to the contents of the RFP are usually not permitted. Interaction between the vendors and the team is usually highly restricted. For example, the program team may not be allowed to meet or communicate with members of a vendor company outside of the channels of communication that are part of the RFP process. Team members participating in developing the RFP should also be prepared to give a detailed list of potential conflicts of interest, based on previous involvement with the each vendor.

Conclusion

Planning and funding a home HD program requires a well-organized effort and close collaboration between clinicians and managers. Up to a year should be allocated for the following:

- A thorough situational analysis of the dialysis landscape, emphasizing the opportunity for a home HD program
- Careful consideration of the clinical and operational characteristics of a proposed home HD program at your institution
- The development of a compelling business case, highlighting the clinical and organizational benefits of a home HD program
- Careful construction and evaluation of an RFP

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