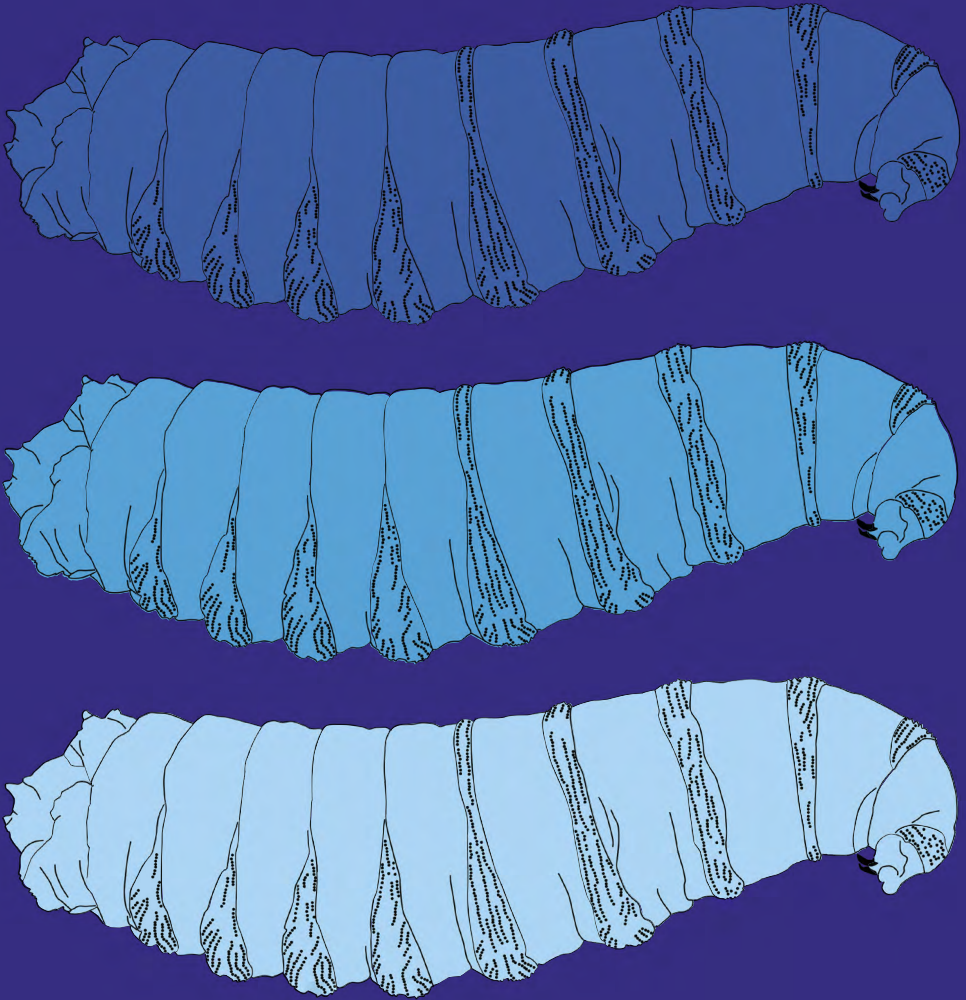


A COMPLETE GUIDE TO MAGGOT THERAPY

Clinical Practice, Therapeutic Principles,
Production, Distribution, and Ethics



EDITED BY FRANK STADLER



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6. Clinical Integration of Maggot Therapy

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The integration of maggot therapy into clinical practice is not a trivial undertaking as it has to overcome social, regulatory, clinical, organisational, financial, and supply-chain-technical barriers. For example, rejection of the therapy by patients due to the 'Yuk' factor is frequently raised as a reason why maggot therapy will not be feasible. Likewise, logistics problems often hamper reliable supply. This chapter identifies these barriers and shows that in some instances they may be more assumed than real, as is the case with the 'Yuk' factor, and that there are tangible solutions for the implementation of maggot therapy programmes, such as supply-chain innovations or socially-minded business models that prioritise patients over profits. In addition, there is a growing body of information and training resources available from medicinal maggot producers, practitioner organisations, and biotherapy advocates that supports the establishment of maggot therapy programmes.

Introduction

This chapter describes a range of factors relevant to the adoption and integration of maggot therapy into clinical practice. Readers of this book are, perhaps, less averse to considering maggot therapy, however there is a well-recognised 'Yuk' factor associated with maggots [1–5]. Distaste for flies or maggots may inhibit healthcare professionals from offering

this therapy as many assume, or claim, that their patients will not accept this therapeutic option.

There are also specific logistical considerations associated with maggot therapy, such as availability, rapid transport of this highly perishable product, temperature and humidity control during transport and storage, clinician training, patient and family-member education, infection control, and waste management, just to mention a few. These and other potential barriers to adoption are considered throughout this chapter, with an emphasis on providing pragmatic solutions and exploring further avenues for implementation.

Fly maggots have been used in wound management 'from antiquity,' as colonisation of the wound by wild maggots (myiasis) was welcome, or maggots were applied to the wound on purpose [6]. Indeed, Mayan tribes in Central America, the Ngemba Aboriginal tribe in Australia and the Hill Peoples of Burma were some of the earliest adopters of maggot therapy [7–9]. Apart from medicinal maggots, there are other examples of invertebrate species that have been used in wound management including ant-heads, bees and honey, leeches, and cobweb [10–12]. While suturing of wounds with ant-heads and cobwebs may have fallen out of common usage, leeches, medical-grade honey, and maggot therapy continue to be employed today.

Despite myiasis of war wounds being considered fortuitous by several military surgeons on far-flung battlefields [8, 13, 14], Western medicine did not see the intentional introduction of larvae until the American orthopaedic surgeon, William Baer (1872–1931), began his landmark studies in the early twentieth century. Baer publicly reported his successful management of chronic osteomyelitis with *L. sericata* at a conference in 1929 [15]. A posthumous publication followed two years later [16], detailing maggot therapy in over a hundred children with complex wounds and osteomyelitis. While clinical results were favourable, secondary infection with *Clostridium tetani* and *Clostridium perfringens* led Baer to further introduce sterilisation procedures [16]. Although the origins of maggot therapy are very much non-sterile, today, medicinal maggots are of high quality and disinfected prior to treatment.

Institutional and Professional Considerations

The establishment of maggot therapy services is commonly frustrated by a lack of support within the wound care team or from administrators [17]. The *Biotherapeutics, Education and Research (BTER) Foundation* [18, 19] produce a wealth of resources to support the adoption of maggot therapy, including template documents to support the development of policies and procedures (<https://www.bterfoundation.org/policies-procedures-templates>).

Wound care is delivered very differently depending on each country's systems of care, healthcare-provider blend, and clinical settings. For these reasons, the introduction of any new treatment is challenging. Sherman and colleagues [17] identified potential professional boundaries, including insistence that maggot therapy be applied by medical professionals and/or within the in-patient setting. These authors pragmatically recommended compliance and compromise with such requirements in the first instance, with review after successful roll-out.

The *NHS Five Year Forward View* [20] and the *NHS Long-Term Plan* [21] that followed both highlighted the need to use innovations to improve healthcare delivery within the prevailing financial constraints. Whilst the NHS is often seen as a world leader in developing technologies, it has also been criticised for the slow implementation, dissemination and subsequent day-to-day use of innovative technologies. Adoption timescales must also be shortened from an estimated seventeen years for new technologies to be adopted at scale by the NHS [22]. Reasons offered include organisational inertia, local custom and practice. The slow uptake of new therapies poses a significant challenge in the West but in resource-limited settings, adoption of new therapies may take even longer [23]. Patent protection and prohibitive pricing further contribute to a lack of adoption of new therapies in both high- and low-resource settings. Maggot therapy is not a novel therapy and has a long and outstanding safety record and the wealth of supportive evidence should be highlighted when discussing the adoption of maggot therapy and overcoming the “*not in my backyard*” mentality that may prevent lead clinicians and administrators from initiating this therapeutic modality [17, p. 29].

Increased harmonisation and adoption of regulatory approaches between jurisdictions may reduce issues associated with views of maggot therapy as a ‘new therapy.’ The proof required for new innovations to be adopted into routine clinical use far outweighs the proof required for established practices. New innovations often require conclusive, randomised, controlled studies or meta-analysis evidence before adoption. Whilst at first glance this may appear laudable, the opposite is true of more established clinical routines or innovations. Established clinical practices often have low evidence of efficacy and are instead taken on trust [24].

Regulatory Considerations, Cost and Reimbursement

The cost of maggot therapy treatment and therefore its demand and availability in a particular location is closely linked to the regulatory status of the therapy and whether health insurers subsidise it. It is important for pioneers of maggot therapy in new jurisdictions to consider this interplay of design production and care systems that maximise availability and minimise cost to the patient.

Regulators classify medicinal maggots differently around the world. The Federal Drug Administration (FDA) in the US categorises them as a medical device, “for debriding non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers and non-healing traumatic or post-surgical wounds” [25]. Other countries typically regulate medicinal maggots as a drug [26]. Consequently, there is a lack of harmonisation across jurisdictions, which can slow global uptake and implementation of maggot therapy.

How Healthcare Is Paid for

There are four main models that are important to discuss here because they have a significant impact on the integration and delivery of maggot therapy in any particular healthcare setting. These are the Beveridge model, the Bismarck model, the National Health Insurance model, and the Out-of-Pocket model [27]. *The Beveridge model* was first described in *The Beveridge Report: Social Insurance and Allied Services*, paving the

way for the development of the 'Welfare State' [28]. This had the core principle of the state being responsible for health and social support. Key amongst these recommendations was the initial outline of the National Health Service (NHS). This model provides universal healthcare for all citizens, free at the point of use, and is financed by the government through tax payments. This model is currently found in Great Britain, Spain and New Zealand. *The Bismarck model* is a non-profit based insurance system where deductions are made from employees' payroll in conjunction with contributions from employers [29]. It must include all citizens and is found in countries such as Germany, Japan and Switzerland. *The National Health Insurance model* is a combination of the Beveridge and Bismarck models. Funding comes from a government-run insurance programme that all citizens fund through a premium or a tax but delivery is through private companies [27]. This model is found in Canada, for example [30]. In the United States of America (USA), Medicare is a government-financed programme, funded through taxation. Medicare is a type of National Health Insurance programme but with age and situation restrictions, unlike the Australian Medicare system. Uptake of private healthcare cover is higher in Australia and the USA than the UK. In the USA, particularly, many individuals also fall into a fourth, *Out-of-Pocket model*, or payment-on-receiving-care model. This model is found in much of the world [27]. In other words, you pay for care as you receive it. It is used in countries that economically and organisationally cannot provide any kind of national healthcare system. In these countries, those that can pay for healthcare can access it and those who cannot afford it remain sick or die. Examples can be found in Africa and South America but self-payment is also applicable for many individuals living in the USA.

Affordability of wound care to the patient is a significant determinant of maggot therapy programme success. For example, in the UK maggot therapy is reimbursed and therefore in demand, which means there is an incentive for a commercial producer to supply medicinal maggots. In Slovakia, by contrast, EU approval for maggot therapy applies but the health insurance system does not reimburse the treatment, thus making the therapy less affordable to patients, in turn making medicinal maggot supply commercially unviable. In other words, the Out-of-Pocket model makes it most difficult to provide maggot therapy services, especially

if the producers of medicinal maggots seek to maximise profit. Within the wound care context, the National Institute for Health and Care Excellence [31] states that, in the absence of any robust clinical evidence to guide choice, prescribers should routinely choose the dressing with the “*lowest acquisition cost*” appropriate for the given circumstances. Maggot therapy is certainly more expensive than dry or paraffin gauze bandages, mainstays in low-resource settings. However, compared to other advanced wound therapies, medicinal maggots can be supplied at a very low cost, provided supply chains are efficient and business models do not prioritise profit.

Another consequence of high out-of-pocket costs is that the therapy is seen as a ‘last ditch’ or ‘last resort’ [32, 33]. For example, in the United Kingdom larvae are now available on prescription which is due to effective lobbying by the producer and sympathetic clinicians. Courtenay [32, p. 178] conducted telephone interviews with nurses experienced in maggot therapy in the UK. One nurse said, “in the majority of cases, larval therapy was used when all other forms of wound treatment had failed” and another nurse respondent typified this approach by stating “we tend to have tried everything else before the maggots, they are the last-ditch attempt”, and yet another said that “originally, maggots were last-ditch. They can be first-line treatment now”.

To summarise, in jurisdictions where maggot therapy is approved and subsidised or paid for through national insurance schemes, maggot therapy has become a frequently used wound care modality. Effective lobbying by producers and clinicians who champion the therapy to secure health insurance coverage is therefore a critical part of the introduction of a maggot therapy programme in a new jurisdiction. In places where medicinal maggots are not subsidised, producers must adopt highly efficient business processes or socially-minded business models to make medicinal maggots affordable while still ensuring business viability.

Case Study: Negative Pressure Wound Therapy

There are many differing models of resourcing healthcare and the confounding issues of differing classification of maggot therapy have also led to a multitude of different options and complications

for reimbursement. This too has contributed significantly to a lack of standardisation of usage. Compare this to another wound care technology, developed at a similar time, Negative Pressure Wound Therapy (NPWT). Initially, NPWT was dominated by the Vacuum Assisted Closure (VAC) model developed by Kinetics Concepts Incorporated (KCI Medical) for many years. The consistency of one company lobbying and developing the technology led to it becoming embedded as established practice. As a result, they developed standardised guidance and subsequent evidence. This helped establish the practice of NPWT internationally. It is, of course, easier to supply and sell a NPWT device to the global market. While the original VAC units were quite bulky and expensive to hire, recent competitor systems have a simpler pump (PICO) or spring mechanism (SNAP) to apply negative pressure and much smaller dressings and portable containers, respectively, for exudate collection and disposal [34].

In comparison, “there are few commercial producers of medicinal maggots around the world and production is mostly small in scale” [35, p. 2]. The largest commercial producers are *Monarch Labs* in the USA and *BioMonde* in Wales, Belgium, and Germany [6, 36, 37]. *Monarch Labs* and *BioMonde* have established their products and services beyond a niche category, with maggot therapy now a widely-used and accepted therapy in these markets.

Logistics and Distribution

Availability of Local Medicinal Fly Species

Logistics and distribution are, perhaps, the greatest factors for the failure to embed maggot therapy into regular clinical practice, especially in low- and middle-income countries (LMIC) with poor logistics infrastructures. It begins with the availability of suitable species in any particular geographic location. The most commonly used medicinal fly species are *L. sericata* and *Lucilia cuprina* [38], though a wide variety of blowfly species have been used effectively in the past [39]. Safety and efficacy are best documented for *L. sericata*, but in regions of the world where that species is not native, most authorities believe it is best to use a local species for maggot therapy, if possible. This is because despite best efforts, medicinal flies will escape from the lab and from the

patient's wound, at some time. From an environmental and regulatory standpoint, it will therefore be much better to use a fly that is native to the area. That is why new blowfly species continue to be investigated. Please refer to Chapter 11 of this book for a detailed discussion of alternative medicinal fly species and the process of bioprospecting and research required for regulatory approval and clinical use [40], and Chapter 13 for guidance on how to collect, identify, and establish laboratory colonies of appropriate species [41].

Distribution Logistics

It is not unusual for physicians and surgeons to order advanced wound therapies in ahead of time. Surgical procedures and certainly sharp debridement can usually be performed at the time of assessment, however. Medicinal maggots need to be ordered 24 (or more) hours ahead of intended treatment, depending on the sophistication of production. As medicinal maggots are perishable and need to be delivered quickly, ideally within the space of 24 to 48 hours from dispatch at 6–25°C [42], the need for temperature control is shared with other advanced wound therapies. Cooling of topical haemoglobin and skin substitutes may require refrigeration, while some graft products, such as xenografts, must be frozen [43–45]. In the case of medicinal maggots, temperature control to within the preferred range during transit and prior to application may be achieved with cool packs [46]. Any transport interruptions jeopardise the health and efficacy of medicinal maggots even if cool-chain packaging is used. This is a problem when servicing rural and remote locations but is particularly limiting in disaster- and war-torn environments where demand for maggot therapy might be high but logistics infrastructure is disrupted or destroyed [47]. Furthermore, a consensus group on the treatment of diabetic ulcers agreed that maggot therapy requires two or three applications to achieve effective debridement, necessitating timely reordering for continuation of the therapy [48]. As a result, a shelf-life of 24–48 hours significantly limits the ability for sufficient quantities to be ordered in advance for such repeat treatment. Seamless reordering and supply over long distances is also more difficult and has limited the ability of any one company to service a large geographic area from a central location.

The perishable nature of larvae raises similar logistical issues to those reported for vaccines and blood products [49, 50]. Cool-chain distribution via couriers remains the most popular method of delivering larvae from production facilities to clinicians. It may or may not include commercial airfreight over long distances. Distribution via military cargo planes and helicopters [51], though physically very demanding on the maggots, has been shown to be feasible, as well as transport via Unmanned Aerial Vehicles (drones) for humanitarian relief missions [52, 53]. For maggot therapy in rural, remote, or compromised healthcare settings, supply chain and logistics innovations are under development that either speed up delivery or locate production at the point of care as described in Chapters 17 and 18 of this book [53, 54].

Treatment Logistics

The application of medicinal maggots and the construction of dressings that keep medicinal maggots in place is highly adaptable to the healthcare setting. Chapter 5 explains the basics of maggot therapy dressings, including the use of ordinary tightly-woven clothing fabrics for maggot dressings, these days a plentiful resource even in compromised healthcare settings [55]. After maggot therapy has been commenced, daily outer dressing changes are necessary to check the viability of the larvae, maintain a moist environment, and facilitate aeration of the wound so that maggots do not suffocate beneath exudate-soaked bandages. Given that a course of maggot therapy takes no longer than 2–4 days, this temporarily increased care burden compares favourably with collagenase, for example, which typically requires ongoing application for months on end.

There may also be additional disposal challenges, particularly in the community setting. After treatment, larvae are usually double-bagged along with soiled dressing materials and disposed of as clinical waste. Stadler [35, p. 5] has explained that clinical safety and infection control are primary considerations rather than “humane treatment of medicinal flies [...] largely because invertebrate animals have not been included in research ethics guidelines, and there has been little research regarding their pain perception, analgesia, anaesthesia and euthanasia.” For a detailed discussion of the ethics of maggot therapy, please refer

to Chapter 19 [56]. In the community setting, if clinicians are unable to collect and return waste to a hospital with clinical waste disposal, the carefully bagged treatment waste can also be disposed of via the municipal waste stream.

Patient and Practitioner Factors

Perception and Acceptance

Maggot therapy punches above its weight in terms of synonyms that have been devised for the sake of social marketing, motivated by the ‘Yuk’ factor [3–5], which is a “*perceived squeamishness and disgust of maggots*” [2]. Among a group of UK Open University students, maggots were ranked as the sixth greatest anxiety-inducing animal, behind snakes, wasps, rats, cockroaches and spiders [57]. From a list of 35 animals, maggots were the most disliked, reported among 46% of respondents [57]. Hence the use of terms like ‘biosurgery’ and ‘larval therapy’ for this modality instead of the ‘M’ word. However, fly larvae are maggots and, at the end of the day, that is the most readily understood term. Besides, when it comes to the time patients need to be informed about the therapy, there is no avoiding the fact that biosurgery or larval therapy involves fly maggots. Therefore, in terms of health literacy and informed consent, ‘maggot therapy’ and ‘maggot debridement therapy’ are certainly more transparent monikers and have been used in clinical practice and the literature alike [35]. Besides, the ‘Yuk’ factor is probably far more prominent among healthcare professionals. Qualitative research, conducted by Courtenay [32], found the ‘Yuk’ factor alive and well among nurses in the UK, with some expressing concerns about escaping larvae. This is why the term ‘larval therapy’ continues to be used, mainly by the UK and European producer BioMonde, and by researchers from this region. However, phenomenological research by Steenvoorde [4] suggests that the ‘Yuk’ factor may be tempered among adults when prescribed by a trusted medical professional. Steenvoorde’s survey captured the attitudes of 37 individuals receiving maggot therapy, none of whom reported negative pre-conceptions and, having received it, 94% would recommend it to others. This finding is particularly pertinent as it would appear our patients are less averse to this therapeutic option than, perhaps, many healthcare professionals

might expect. Recently, Humphreys and colleagues [2] considered the opinions of Welsh schoolteachers concerning the introduction of maggot therapy into primary education to combat the development of fear of larvae. The authors concluded that introducing maggot therapy as a concept earlier in life may reduce the 'Yuk' factor seen among older adults. In the end, the decision as to whether or not maggot therapy should be initiated should consider wound, patient, and healthcare-setting characteristics as discussed in Chapters 3 and 4 [58, 59] and the consent of the patient after factual and unbiased information has been given [56].

For a patient to be able to give informed consent to maggot therapy, all potential risks and the potential expectations and benefits for assessment and treatment must be disclosed, as this will vary for individual patients with differing wounds and medical conditions. Patient and carer guides should also be provided, which patients may wish to share and discuss with members of their family or caregivers. Chapter 19 provides a first-pass discussion of the ethical dimensions of maggot therapy [56].

Clinical Considerations

A full patient assessment must be undertaken prior to initiating maggot therapy, including a full and thorough medical history, comprising i) current medications, ii) known allergies to medications, insects, and products used in the production of medicinal maggots, iii) an assessment of the wound type, underlying diseases, and wound processes, and iv) inspection of the wound bed.

Patients may not be able to accept maggot therapy due to allergies to certain maggot diets or diet-related religious beliefs and customs. Fortunately, there is flexibility in the way medicinal maggots can be produced. Maggots may be fed with meat from a variety of animals other than pork or beef, or even with meat-free diets, thus allowing producers and therapists to tailor maggot therapy to the cultural and religious preferences of the patient [60]. For patients with diabetic ulcers, glycaemic control should be addressed, as must the specific challenges associated with offloading a neuropathic wound on the sole (plantar surface) of the foot or posterior to the heel. Following a complete neurovascular assessment, activity levels and concordance

with offloading modalities should be addressed. If pressure cannot be sufficiently relieved from the wound site, larvae may be crushed by unrestrained compressive forces when standing, walking or in bed, in the case of posterior heel ulceration. A range of offloading modalities are available to reduce direct pressure over the wound site and may include, but are not limited to, customisable, apertured, semi-compressed ('Chiropody') felt. The presence and degree of arterial disease must also be considered, and disease-specific national and international guidance should be followed. Examples include National Institute for Health and Care Excellence Guidance in England and Wales [61] and the International Working Group on the Diabetic Foot Guidance [62]. For ischaemic or neuroischaemic foot ulceration, the level and extent of arterial disease should be determined. There is also a need to consider whether critical limb ischaemia is present and to determine if there is a requirement for reconstruction, such as angioplasty or bypass [63, 64]. Venous ulcer assessment also necessitates a thorough investigation for any co-existing arterial disease, before initiation of compression therapy [65]. Pressure ulcers should be staged [66] and further requirements for surgery explored. Pilonidal sinuses, traumatic wounds and necrotising fasciitis may also be suitable for post-surgical maggot therapy, as are post-surgical wounds that are slow to heal or those complicated by MRSA infection [67].

Wound assessment prior to the application of maggot debridement therapy should be carried out by a qualified healthcare practitioner, according to local policy. Application and evaluation, however, may be undertaken by a competent, trained healthcare worker. A freely available position paper by the BioTherapeutics Education and Research Foundation [68] describes the competencies desirable in a clinician treating patients with maggot therapy. It should inform on the training required of new maggot therapy practitioners. In the UK, free training is available via BioMonde's '*Larval Academy*' and accredited by The Royal College of Nursing and approved by The Royal College of Podiatry [69]. The *BioTherapeutics, Education & Research (BTER) Foundation* in the USA and *The Mexican Wound Care Association* also offer informative and helpful education and training resources on their websites and through publications to support maggot therapy in these settings [19, 70]. However, even where trained clinicians are in short supply, it has

been shown that lay providers in low-resource environments with only basic instructions can support and perform maggot therapy [71].

Organisational Considerations

When introducing maggot therapy, procedures for prescription, ordering, application and monitoring must be established and key care structures must be in place to support adoption of this modality.

Prescription and ordering. The process for prescribing and ordering larvae in the UK has been described in detail in an ‘*All Wales Guidance for the Use of Larval Debridement Therapy*’ document [72]. Prescription and ordering processes and procedures differ between NHS community and hospital settings. An FP10 prescription order, from a registered prescriber or doctor, must be raised if maggot therapy is initiated in the community setting. Hospital orders, in contrast, are typically included on the patient’s prescription sheet. Community or hospital pharmacists then contact the company directly to request the appropriate number and size of maggot containment bags required. Ordering before 2 p.m. will typically permit next-day delivery, from Monday to Saturday. Different countries with different healthcare systems have varying medical goods ordering and procurement practices and medicinal maggot producers need to tailor their production, supply, and sales practices accordingly [73].

Interdisciplinary care and communication. Communication between acute and community services is paramount to ensuring smooth transition of care, both following discharge from hospital or when initiating or continuing collaborative care, guided by acute wound services. Before prescribing and ordering larvae, acute providers must ensure that suitably trained professionals are able to monitor wound progress, maintain optimal moisture conditions and change secondary dressings between pre-scheduled acute service reviews. Daily inspection is typical and should be supported by both written information sheets and verbal handover between healthcare professionals. As part of consent documentation, written information sheets should also be provided to patients and lay carers, to explain maggot therapy and address frequently asked questions. Photographs taken before maggot therapy may further assist in ongoing wound monitoring and

community colleagues could be invited to attend the initial larvae application appointment to observe the process and discuss individual requirements. Reapplication of larvae may be performed following assessment by acute expert clinicians. For plantar foot wounds, there is a further imperative to ensure that adequate offloading is maintained through the course of therapy. While larvae may withstand some direct pressure, without appropriate offloading strategies they may simply be crushed and lose viability [48]. Offloading may be achieved with local application of semi-compressed felt, in combination with deflective orthoses and offloading devices or footwear.

Summary

Maggot therapy is highly efficacious in eradicating offending bacterial species, removing tenacious biofilms and slough, and improving outcomes for people with wounds. Administration of the therapy and application of maggot dressings is relatively simple and can even be performed by lay carers provided basic guidance is provided. However, successful implementation of maggot therapy programmes in any jurisdiction depends on whether maggot therapy is affordable to the patient. Affordability may be achieved via health insurance subsidies or low-cost production and supply. It is easier for producers to make a profit from medicinal maggots where treatment is subsidised. Affordable supply elsewhere must resort to socially-minded, for-purpose business models and/or low-cost production.

Because medicinal maggots are perishable goods and have a short shelf-life, it has been difficult to supply them on a reliable basis in places with poor logistics infrastructure. However, it is clear now that these supply-chain barriers can be overcome with innovative technologies and flexible supply-chain architectures as explained at length in this book [41, 53, 54, 74–76].

Rejection of maggot therapy by patients is another often-cited barrier to its wider use. However, there is good reason to believe that patients with chronic debilitating wounds have few reservations and are more than willing to give maggot therapy a try. Rather than assuming a patient's aversion, clinicians should base their decision as to whether to

use medicinal maggots on actual patient preferences, medical suitability, local wound factors, and cost considerations.

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