Which pill when:
packaging that aids compliance in taking prescribed drugs

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i~design partners

- **The Royal College of Art Helen Hamlyn Centre**, is a centre for inclusive design, with extensive contacts in industry and the design professions.
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- **Applied Computing** at the University of Dundee develops information technology systems to support older and disabled people.
- **The HCI Group** at the University of York has a long history of inter-disciplinary research in the area of user centred design arising from collaboration between the departments of Psychology and Computer Science.
- **The Design Council** inspires and enables the basic use of design by business, education and government to improve prosperity and well-being.

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Abstract

GlaxoSmithKline (GSK), the industry partner in this project, was concerned about the problem of non-compliance in taking drugs. It prompted them to initiate this study into the means by which compliance could be integrated into medicine packaging. Many compliance aids have been introduced on the market but the problem of non-compliance persists. At an annual cost is estimated at £60 billion worldwide. Mawle undertook the first year of the study and was joined by McGinley for the second and final year of the work during which the user network was expanded further to include, among others, medical professionals. At the outset of the study, existing compliance solutions were analysed. The exploratory design studies which followed generated a range of off-pack memory aids. A user group of 12 people was formed and their usage patterns observed. These provided key insights into common patterns of user behaviour. As part of the study, the compliance problem was 'deconstructed', and three design proposals emerged: the Access Pack, which included an access aid as an intrinsic part of the packaging; the Moving Pack, incorporating a diary and a special detachable box to support discreet use of packaging when on the move; and the Remind Pack, with a collection of prompts that can be placed around the house as personal reminders. These formed the centrepiece of a special compliance kit produced at the end of the project. It provided design guidance on the issue to GlaxoSmithKline's in-house design teams. The case study demonstrates how in-depth research into long-standing problems can open up hitherto unexplored integral, low-tech solutions to provide high-value solutions.

Keywords

Medical non-compliance, prescription pills and medicines, medication users, compliance aids, design guidelines, packaging.

Project period

October 2002 – October 2004

Overview

The giant strides that have been made in pharmaceutical research and development can be undone by the simple fact that people do not take their medication as prescribed. Medical non-compliance of this kind in the USA is responsible for one in ten or 3.5 million of all hospital admissions [1] and a quarter of all nursing home admissions [2]. The problem will be exacerbated as the population ages - by 2020 it is expected that one in every two European adults will be over 50 [5]. Older patients take three times as many drugs as the general population and their rate of non-compliance is reckoned to cost the

UK economy some £3 billion every year with more than 50% of all medication prescribed in the USA being taken incorrectly or not at all [3].

The issue of non-compliance must be addressed at every stage or manufacturing interface in the process: from the prescribing GP (General Practitioner) via the pharmacist to the patient or carer. Each of these parties needs to recognise and be aware of the benefits of a well-designed manufacturer's medication pack.

The study commenced with the setting up of a project steering group consisting of 10 members of GSK staff representing: research &

development, product and packaging development, pharmaceuticals, and manufacturing. Two meetings were held to set out and discuss the background parameters, which were subsequently collated into seven areas of interest:

- Criminal (particularly parallel imports or redirection of prescription-only medicines [POMs] to take advantage of international price differentiation; patent violation; redressing or repackaging of pills that have expired; substitution, and clocking - where expensive inhalers with a dose meter are reset to obtain free replacements)
- Financial
- Legal
- Manufacturing
- Physical
- Stakeholder (all those involved in the compliance, prescription and buying/distribution chain, particularly packaging. This latter aspect should be inclusive - avoiding hindrance to visual, cognitive and muscular function)
- Marketing

It was agreed that the focus of the project should not be to create yet another new compliance aid, but that through further study medication packaging should become a more integrated part of medicine compliance, thereby avoiding electronic devices with their associated issues of sustainability and recycling.

A second round of meetings followed. These focussed on the most important aspects which had emerged, namely: identification of GSK products suitable for user testing (Augmentin, Avandia, Avodart, Seretide (Advair – USA) and Seroxat (Paxil – USA), issues of child resistance, the importance of disease awareness (reminding patients of the

implications of non-compliance), and transferability to the USA market.

As is customary with the HHRC Research Associates Programme, the first one-year project was divided into four stages:

Stage 1: Explore (October – December)
Stage 2: Focus (January – March)
Stage 3: Develop (April – June)
Stage 4: Deliver (July – September)

Methods

As the 'explore' stage progressed, literature and product searches were undertaken from which the following categories of existing product were identified: Desktop, Holder, Personal, Prompt, Prompt/holder, Re-packing/chart, Third party

In conjunction with the industry partner, seven criteria were identified in order to assess and compare the product types. They were: low cost, minimisation of stigma (privacy), portability, record compliance, regulation of dosage, reminder to user, and storage (removal to a separate container being considered undesirable). The products were placed in a matrix to represent their relative weaknesses which highlighted the following generic issues: record compliance, regulation of dosage, reminder to user.

Initial interviews were held with general practicioners and pharmacists. These revealed that doctors' workloads mean that they do not have time to give advice on compliance. As a result, when patients return with other symptoms, it is difficult to know whether these are due to side effects or non-compliance. Patients also tend to ask for branded drugs because of their superior labelling (such as the inclusion of days of the week) and their use of perforations to improve ease of handling. Pharmacists often have to educate patients about their

Category	Example
Immediate	Asthma – Ventolin
Short-term	Antibiotics – Augmentin
Medium Term	Antidepressant – Seroxat
Long Term type 1	Blood pressure – Cohmadin
Long Term type 2	Enlarged prostate – Avodart
Long Term type 3	Type 2 Diabetes – Avandia

Table 1. Six key areas of medication

medication. Generally speaking, patients were found not to read the patient information provided with the pack, and pharmacists are their first port of call when they experience difficulty with their medication.

A categorisation of drug regimes was then compiled from which six key areas of medication use were identified as shown in Table 1.

- Immediate
- Short-term
- Medium Term
- Long Term type 1 (patients who show little symptomatic improvement over the short term, few perceivable side effects, yet the regimes must be carefully followed long term to prevent a grave attack of symptoms)
- Long Term type 2 (patients with a drug regime to treat the cause of a major disease such as an enlarge prostate or the symptoms in other cases)
- Long Term type 3 (patients with a long-term drug regime that may have a delayed effect on symptoms after the treatment commences. If the regime is interrupted then the return of the symptoms is delayed and unlike previous categories there is no discernible attack from the underlying disease and treatment can recommence without side-effects)

A user group was identified which initially consisted of twelve interviewees. These were selected for their lifestyle, drug regime and age and were invited to complete a questionnaire. Questions were both open-

ended, allowing participants to submit more involved answers, and structured, allowing both qualitative and quantitative data to be collected. Information from completed questionnaires was then used to direct one-to-one formal and informal interviews with each user, and a Medication diary (plus disposable camera) left with the interviewees to complete at their leisure. These diaries allowed analysis over a longer period and presented issues that would not otherwise have been apparent. Observations also took place as continuous routines, such as those developed by medication users. These are almost subconscious hence the need for observation was of great importance. Forums of six to eight users were also set up to discuss general compliance issues and to evaluate prototypes.

Each user was profiled using information from the completed questionnaires. Six users were selected, each of whom fitted into one of the categories identified above (immediate, short-term etc). They were also selected for their range of ages (from their 20s to 50s), the range or number of pills taken, ie. from 1-11, and their willingness to participate further. In-depth anecdotal records were then compiled as shown in Figure 2.

Results and design Outcomes

Further discussions with the research partner revealed that the following types of non-compliance prevail and that patients may be guilty of one or sometimes many of these practices:
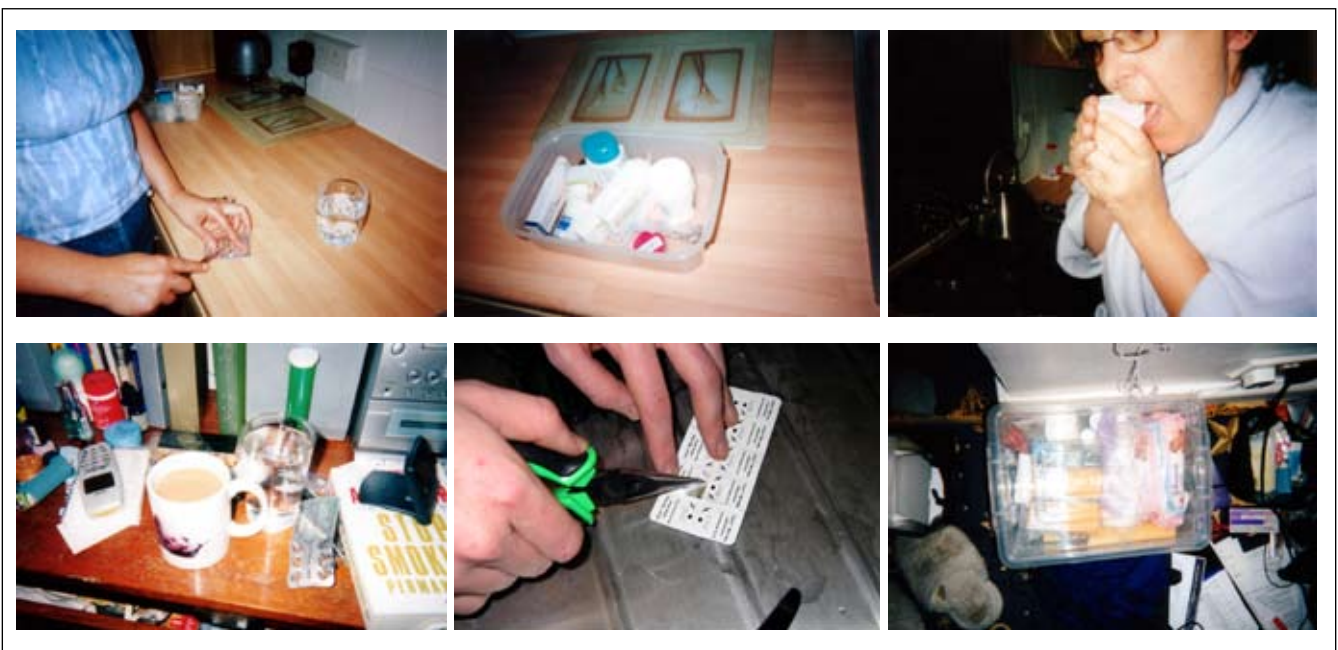

Figure 2. Anecdotal visual records of styles of use

- Failing to take a prescribed medication
- Taking the medication for the wrong reason
- Taking the medication at the wrong time or in the wrong sequence
- Taking someone else's medication
- Hoarding old medication to take later
- Taking the prescribed medication in combination with a potentially interactive medication that has not been prescribed.

However, the idiosyncrasies and rituals of everyday life tend to govern the reality of pill-taking - not only do personality, age and ability contribute to non-compliance but there is a link between the type of medication and the quantity of different drugs taken. The following comprehensive list of reasons for non-compliance was drawn from user experience as opposed to the more commonly quoted statistical analyses.

- **Cognitive decline** due to age, illness or the effects of the drug(s)
- **Effects of the treatment** take time to be felt – thus, stop taking pills
- **Patient lacks organisational skills**
- **Hoarding** old medications to take later
- **In hospital for unrelated reason** (or similarly incapacitated) – how is compliance upheld?
- **Lifestyle incompatibility** – if pills react with alcohol this could affect social activities; prescription prevents performance at work
- **Taking pills for the wrong reason** – e.g. antibiotics for flu/cold
- **Too many different pills** being taken – leads to confusion
- **On the move** – compliance is inconvenient
- **Treatment eases symptoms** – Therefore individual stops taking pills
- **Overdose** – perhaps symptoms are very bad, leading to increased self-dosing

- **Value personal opinion** over that of GP/Specialist
- **Physical barrier to compliance** – problems opening packaging or actually ingesting medication
- **Waste Not Want Not** – if the drug appears to have served its purpose, or is having no perceivable effect it may be put aside for the future. This attitude not only leads to non-compliance at the time, but could also mean self-prescription in the future
- **Lack of personal willpower** or desire to comply
- **Reading instructions incorrectly** – size/clarity of pharmacy instructions or language barrier
- **Remembering whether pills have been taken** is as much of a problem as remembering to take them
- **Wrong time/wrong sequence** – drug may require very specific conditions e.g. empty stomach
- **Sharing medication** on purpose or by accident
- **Short-term medication**, habit of compliance never forms
- **Taking medication with non-prescribed drugs** e.g. a flu remedy.

From this it became clear that there were three main areas that affected the individual's 'compliability': character and complexity or length of medication routine, all of which underpin all aspects of compliance.

The research-specific output themes highlighted the following five key issues with users' pill compliance:

Remind
Individuals developed their own strategies for integrating medication taking into consideration their own lifestyles and cognitive disposition, such as putting the medication packet by the toothpaste in the bathroom to remind them to take it twice daily. Users commented that the trigger did not have to have a connection to the medicine - which led to
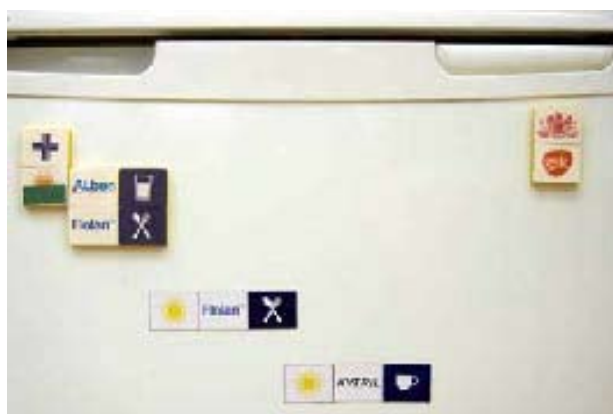

Figure 3. Pop-up reminder

Figure 4. Fridge magnet

the generation of off-pack ideas, such as the pop-up reminder (Figure 3), the TV guide stickers and Fridge magnet concept (Figure 4). However, some medicine directions are very time/situation specific, which means it is not always possible to leave pills situated in one location. Putting medication with other core activities can be inhibited if users are: generally disorganised, lacking in willpower or desire to comply, on short-term medication, or on the move, particularly when pills have to be taken with a meal.

Access/consume
Problems highlighted by the user research included:
- lack of control and stability when opening blister packs or removing safety caps
- lack of precision of dose control (liquids)
- coping with the weight of some liquids needing three hands – two to pour, one to hold the spoon
- cognitive decline due to age, illness or the effects of drugs
- difficulty in reading small text, and complying with specifics such as taking medicine on an empty stomach.

Record/renew
There were widespread problems of forgetfulness with no provision for recording whether or when doses had been taken (such as on the pack – which would need to be individually tailored to suit each patient's medication regime). It was also thought advantageous for pharmacists to produce individual patient medication routines.

Transport
Coping with holidays and other absences from home posed significant problems and a specific brief began to emerge for a new design of transport packaging to include perforations and individual labelling, drug naming, dose and expiry dates, protection and provision for the remind function.

Patient Information
The way in which patient information is incorporated into the medicine pack and the nature of the information provided in order to comply with legal criteria mean that this critical item is very often eliminated and/or simply ignored. A specific brief

Figure 5. Access Pack (version1)

Figure 6. Moving Pack (version1)

Figure 7. Remind Pack (version1)

emerged from the user research addressing clarity of information and discouraging the hoarding of out-of-date medication.

Three design solutions were developed from the work to date and prototypes produced:

• **Access Pack (Figures 5)**
Packaging that provides a built-in aid to dispense pills from the blister pack. This includes an intrinsic access aid and clear, concise jargon-free patient information.
Features:
– **Patient information:** this is a quick reference panel to highlight certain aspects of the patient information leaflet included with the pack. It reiterates the most important issues that relate directly to the patient.
– **Icons:** In order to help patients take their medicine at the right time of day, these easy-to-read universal icons are used.
– **Blister pack information:** it is important that each individual pill is labelled with the drug name and dose, so that if the pack is split, the pills retain their identity.
– **Access Aid:** an intrinsic part of the pack, this plastic part enables patients to more easily "pop" tablets out of the blister pack.
– **Window:** a quick visual reference to check on the amount of medicine remaining in the pack, giving patients a reminder to order repeat prescriptions when they see their tablets are running low.

• **Remind Pack** (Figures 7)
A pack that assists recall and recognition issues and includes compliance prompts and also documents the patient's place in their medication routine. This workbook-style pack includes individually tailored 'Patient's Cards' that can be printed out by pharmacists.

Features:
– **Individual Patient Card:** Pharmacist prints out a Patient Card individually tailored to the patient's regime, showing day and time that each individual pill should be taken.
– **Place in the process:** the Patient Card provides a visual reference for the patient to see where they are in their regime. The patient marks the card every time they take a pill. Retaining the cards provides a record of the full course of medicine.
– **Instructions:** when an empty blister pack is removed, the next blister is visible. The Patient Card should be changed at the same time.

• **Moving Pack** (Figure 6)
A pack for those on medication whose working lifestyle is mobile. The pack is timetabled, has tear-off doses for the workplace and weekend and includes portable pouches for the protection and visibility of pills in the daily landscape.

Features:
– **Portable pouch:** a pouch that carries a strip of medication for when you are away from home. It is a visible, yet subtle, protective item – fitting into the patients work life or leisure time.
– **Days of the week labelling:** blister packs include 'days of the week' labelling for individual pills. This helps the patient to quickly see where they are in their regime.
– **Blister pack information:**it is important that each individual pill is labelled with the drug name and dose, so that if the pack is split, the pills retain their identity.

Assessment
The prototypes were tested using the following four user groups which included a professional medical group of medical professionals:

• **Specific Sufferers**: to gain an insight into compliance regarding chronic long-term medical conditions – largely asthma and arthritis (user group of 6 suggested by HHC). In addition, six participants from Asthma UK and Age Concern contributed via forum sites and all twelve were asked to complete a questionnaire detailing problems with medication, compliance aids, previous packaging experiences and analysis of the three prototypes.
• **Disability Issue Group**: to gain an insight into compliance relating to mobility impairment and more complicated difficulties (user group comprising of disabled people attending the annual Mobility Roadshow [A]). Feedback included comments regarding the need for larger medication capacity in the proposed Moving Pack; concerns about its security of closure and difficulties with the Access Pack (eg. pills becoming wedged to the foil when opening the blister pack.
• **Diverse Capability Group**: to gain an insight into a broader ability cross-generational group (user group of 6)
• **Medical professionals (Pharmacists, cares, nurses etc)**: to gain an insight into compliance and packaging from a different perspective.

Twelve pharmacies were mailed questionnaires initially. Since only two replies were received, seven of the same pharmacies who had agreed to cooperate were subsequently visited to obtain information.

The above tests were carried out on prototypes that were being developed and improved during the process. The medical professionals – who were consulted throughout the process – provided comments that were ultimately directed towards solutions that had already passed through several iterations of design improvement. The pharmacists suggested that spaces be provided for stickers on the travel pouch and had concerns about the size and shapes of the boxes which would impact on shelving space. They also favoured standardisation of sizes wherever possible.

Discussion

The work highlighted the need for further revisions and two more phases of design iteration were subsequently carried out, three embodying first stage improvements (Figures 5-7), and three incorporating further enhancements. Figures 8-10 show the finalised versions of Access, Remind and Moving Packs. The features are as follows:

Access Pack – incorporating an easy-to-open matchbox-style slide mechanism and patient information in quick reference panels within the pack. This eliminated the need to turn the box over to remove blister packs from the outer packaging. It was felt that this would encourage the patient to refer to additional information. In addition, a lightweight foam insert enabled pills to be 'popped out' more easily.

Remind Pack – a 'next blister visible when empty pack removed' system displaying the current week of programme, also:
• incorporation of on-pack reminder card with sheets of removable stickers/magnet for personal reminder purposes.
• lengthways orientation to allow greater entrance area for blister removal.
• blister packs internally separated with the inclusion of cut-outs for finger/thumb access.
• locking mechanism incorporated giving a physical and audio cue when correctly opened and closed.

Moving Pack – protective design incorporating an information flap, aesthetically designed to fit the patient's work life and leisure time.

Figure 8. Access Pack (final verion)

Figure 9. Remind Pack (final verion)

Figure 10. Moving Pack (final verion)

These proposals were then enhanced in the light of a further literature review [4] and in consultation with a packaging design group. The objective was to retain the full functionality of the final exemplars.
    A compliance kit was then developed containing

Figure 11. Springboard cards

Figure 12. Simulation glasses and gloves

the following items:
- Instruction booklet
- Exemplar packs
- CD-ROM containing visuals of users and comments made in regard to medication packaging.
- Springboard cards – highlighting issues and presenting provocative visuals in relation to compliance to stimulate the design process (Figure 11). They incorporated metaphors, design concepts and unusual existing techniques
- **Simulation tools** – to simulate physical conditions such as arthritis, glaucoma, cataracts and macular degeneration to facilitate a more informed and empathic analysis of packaging proposals (Figure 12)

Inclusive design principles were embodied throughout the development of the final solutions, which feature broad patient appeal. The physical appearance consciously avoided that of a product designed for the older or disabled user. Nevertheless the design solutions took account of the physical, sensory and cognitive problems older users face. Attention was paid to the forces and other ergonomic factors involved in handling the range of proposed medication packs.

The process of consulting users before and after the construction of first stage prototypes was highly beneficial to the effectiveness and user acceptability of the final solutions. These also benefited from the provision built into the schedule for a series of design iterations.

Conclusions and future work

The main conclusions are as follows:
- Allowing for multiple stages of design iteration can be highly beneficial to the effectiveness of the final design solution;
- Taking the physical impairments of the older user into account in the design process need not prejudice the broad aesthetic appeal of products;
- Compliance kits can be a useful way of proliferating accumulated knowledge in this particular context.

In addition to the compliance kit idea which is being adopted by the research partner, the construction of ten kits of the final designs was commissioned for internal distribution by the innovations section of GlaxoSmithKline, and the project featured in their quarterly internal magazine. The research partner has since commissioned a further compliance related-study, which will focus on communications aspects [B].

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About the research partners

GlaxoSmithKline: is a world leading research-based pharmaceutical company with a combination of skills and resources that provide a platform for delivering strong growth in today's healthcare environment. It has 85 manufacturing sites in 37 countries and manufactures almost 4 billion packs per year. GSK's mission is to improve the quality of human life by enabling people to do more, feel better and live longer. *www.gsk.com*

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The Helen Hamlyn Centre was set up at the Royal College of Art in January 1999 to alert design and business to the far-reaching implications of a rapidly changing society. It works to advance a socially inclusive approach to design through practical research and projects with industry. Its Research Associates Programme teams new RCA graduates with industry partners. *www.hhc.rca.ac.uk*

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